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ABSTRACT

Intended to assist Agency for International Development (AID) officers, advisors, and health officials in incorporating health planning into national plans for economic development, this seventh of ten manuals in the International Health Planning Methods Series deals with pharmaceutical supply systems planning in developing countries. Following an introduction to the topic (chapter 1), chapter 2 describes the scope and intricacies of the sector. Useful as a reference guide, the chapter is organized into four main sections: (1) definitional issues, (2) national pharmaceutical policies as affected by political and economic forces, (3) types of systems and subsystems in the pharmaceutical field, and (4) governmental intervention. Chapter 3 identifies and sets parameters for the main components of a comprehensive pharmaceutical supply system. Chapter 4 discusses geeral approaches and methods to planning and assessment. Discussion in chapter 5 centers on problems of distribution to rural populations. Appendixes provide information on development planning for a pharmacy in a small hospital and local issues and approaches relative to local production of medicinal chemicals. Lists are also given of selected planning and assessment aids and international data sources. A supporting document in the International Health Reference Series containing an annotated bibliography is available separately as CE 024 227. (YLB)

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International Health
Planning Methods Series

7

Pharmaceutical Supply System Planning

Guidelines for Analysis of Pharmaceutical Supply System Planning in Developing Countries

U.S. DEPARTMENT OF HEALTH
EDUCATION & WELFARE
NATIONAL INSTITUTE OF
EDUCATION

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Guidelines for Analysis of Pharmaceutical Supply System Planning

U.S. Department of Health, Education, and Welfare
Public Health Service
Office of the Assistant Secretary for Health
Office of International Health

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PREFACE TO THE SERIES

The International Health Planning Methods Series has been developed by the Office of International Health, Public Health Service on request of the Agency for International Development.

The series consists of ten basic volumes which cover a variety of health issues considered vital for effective development planning. These ten volumes are supplemented by six additional works in the International Health Reference Series, which list resource and reference material in the same subject areas.

The International Health Planning Methods Series is intended to assist health sector advisors, administrators and planners in countries where the Agency for International Development supports health related activities. Each manual attempts to be both a practical tool and a source book in a specialized area of concern. Contributors to these volumes are recognized authorities with many years of experience in specialized fields. Specific methods for collecting information and using it in the planning process are included in each manual.

The six supporting documents in the International Health Reference Series contain reports of literature surveys and bibliographies in selected subject areas. These are intended for the serious researcher and are less appropriate for broad field distribution.

The volumes in the International Health Planning Methods Series contain the collective effort of dozens of experienced professionals who have contributed knowledge, research and organizational skills. Through this effort they hope to provide the AID field officer and his host country counterparts with a systematic approach to health planning in developing countries.

PREFACE TO VOLUME SEVEN

This manual deals with the subject of pharmaceutical supply systems planning in developing countries. It is the seventh volume in a series of works known collectively as the International Health Planning Methods Series.

The series was produced by the Office of International Health as requested by the Agency for International Development to provide AID advisors and national health officials in developing countries with critically needed guidelines for incorporating health planning into national plans for economic development.

Generally less is known about pharmaceutical supply systems than about the overall health care systems of which they are an integral part. Particularly in rural areas of lesser developed countries, the pharmaceutical supply system can be a critical part of the health care system.

Evidence suggests that no country possesses an ideal pharmaceutical supply system and virtually all supply systems are affected to some degree by issues and policies outside the nominally controlling field of medicine or health care. A nation's pharmaceutical supply system can be expected to reflect in some degree policies more directly concerned with politics, economics, education and law, as well as those governing medicine and public health.

This manual has been developed in order to provide objective guidelines to assist health care planners to develop improved pharmaceutical supply systems within the framework of national development planning. Particular emphasis has been placed on the importance of making pharmaceutical products available to the rural poor segment of the LDC population.

Preparation of this volume was undertaken for the Office of International Health by S.R.I. International, functioning as a subcontractor to the E.H. White & Co., management consultants of San Francisco, California. The primary author of this manual was Leif Schaumann, health industry economist, who was assisted by Martin M. Rosner of San Francisco State University and John M. Morson, president of McKesson International, who served as manual advisors. Mr. Henry Chuck substantially edited the original text, and added chapters five and Appendix A in this volume.

In many lesser developed countries, essentially "western" concepts occasionally conflict with traditional or indigenous systems for providing health care. Provision of pharmaceutical supplies, therefore, must take place within an existing culture and must accomodate traditional expectations if the system is to be used effectively by the resident population. This essentially local bias must be weighed against the fact that pharmaceutical supply issues tend to be transnational in nature, and LDC governments often seek guidance in this area by adapting the experiences of planners in the United States and Europe.

The research emphasis in this manual has been placed on developing a conceptual framework that is useful as an overall analytical model of an "ideal" pharmaceutical supply system. Adaptation from the ideal can be made to accomodate local needs and resources.

Product coverage of this manual is limited to pharmaceuticals for preventive and therapeutic use on humans. Also, while some discussion has been included on the subject of indigenous medicine and traditional remedies, the predominant orientation of this manual is toward provision of "western" pharmaceuticals.

The author and contributors to this manual have frequently expressed personal points of view with reference to specific pharmaceutical supply systems and projects. While their viewpoints generally coincide with organizations or agencies with whom they are associated, the material in this text should not be construed to reflect the official policy of any agency or organization.

It is hoped that the material contained in this work will assist planners to develop more effective pharmaceutical supply systems dedicated to the provision of improved health care in developing countries.

Paul Ahmed

Paul I. Ahmed
Project Officer
Office of International Health

ACKNOWLEDGMENTS

Each volume in the International Health Planning Methods Series has been the work of many people. In addition to the primary authors, each manual has involved government reviewers and reviewers from positions outside government, editors, revisors, and numerous technical and support personnel. Substantial contributions have been made by manual advisors, who provided the authors with the benefit of their knowledge and experience in the fields under study.

With reference to Volume 7: Pharmaceutical Supply Systems Planning, special thanks are in order for contributions mady be Martin M. Rosner and John M. Morson.

Gratitude is acknowledged to Henry Chuck, who substantially revised the original text.

Acknowledgments are also due to Joe Hackett and Irv Taylor.

While the present work could not have been completed without the assistance of these individuals, responsibility for the content of this manual rests solely with the authors.

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CHAPTER ONE

INTRODUCTION

A comprehensive pharmaceutical supply system is a highly complex mechanism which consists of numerous functional, evaluative, and motivational subsystems. Many of these are purely conceptual in nature, but nevertheless essential for analytical purposes.

Martin Rosner puts it well in his "Quality Control Paper" for this manual: "Due to the somewhat loose interrelationships between parts of the complex, there is reasonable cause for not regarding it as a system at all. The decision to define it as a system has methodological and analytical advantages. The systems orientation enhances understanding of the functional interdependence between parts of the complex and between the complex and the health sector and the general national environment. In addition, this orientation will help overcome the problem of international comparability. Parts of the system may differ radically in form of organization and in sophistication of personnel among LDCs. Comparing national systems by comparing their parts is almost impossible. A systems orientation allows the analyst to assess the situation in terms of how effectively the system performs the various functions that contribute to the overall pharmaceutical health care goal."

A pharmaceutical supply system for the rural poor in LDCs cannot operate in isolation from the general rural or, indeed, the urban pharmaceutical supply system because of numerous cross links. To function, any micro-system must fit with the overall macro-system.

The multitude of dependent variables and the lack of independent variables present the chief obstacles to efficient planning and management of the pharmaceutical sector. Therefore, it is essential to understand how some of these variables interact in the macro-system. This manual fosters such know-how by using a three-pronged approach, as embodied by each of the following three chapters.

Chapter Two, which follows, provides newcomers to the pharmaceutical field with some background and insights into the scope and intricacies of the sector. Simultaneously, the chapter is an easy reference guide for more experienced sector planners and analysts and will provide manual users with a broad understanding of the dynamic forces that impact the pharmaceutical sector. It becomes clear that "change" is a key characteristic.

The chapter is organized into four main sections. First, the definitional problems associated with the words "drugs," "Pharmaceuticals," "medicines," etc. are discussed, and it becomes apparent that these terms are far from clear and are used in many different contexts. The second section of Chapter Two deals with national pharmaceutical policies, and the forces that shape them. A major theme here is that political and economic factors are more significant than health related concerns; the same recognition emerges from other segments in the manual.

The third section of the chapter provides overview discussions of various types of systems and subsystems in the pharmaceutical field, including some that characterize LDCs. The fourth main section of Chapter Two deals with government intervention in the pharmaceutical sector. The major discussion is devoted to some key regulatory tools and issues and the rationale for government intervention.

Chapter Three identifies and sets parameters for the main components of a comprehensive pharmaceutical supply system. The discussion is organized into three main systems parts: A functional, an evaluative, and a motivational framework, each consisting of the following elements:

Functional	Evaluative	Motivational
Product Assortment	Access and Demand	Driving Forces
Product Selection	Quality Assurance	Private Property Rights
Procurement	Utilization	
Domestic Production	Cost Parameters	Liability
Distribution and Storage	Integration with the Health Care System	
Inventory and Financial Control		
Pricing		
Promotion and Information		
Research and Development		
Financing and Payment		

Insufficient resources were available for this manual project to develop a cohesive framework for the motivational aspects of a pharmaceutical supply system, however, a beginning in this direction has been made.

The information in Chapter Three constitutes the central focus of this manual. The thought behind it is that any pharmaceutical supply system, whether viewed from a macro perspective or from a micro perspective and irrespective of its configurations, evolves around these elements.

Chapter Four is very brief. It discusses some general approaches and methods to pharmaceutical sector planning and assessment, and emphasizes that in any pharmaceutical project: "First, the mission must be clearly defined. This is typically a much more complex undertaking than generally recognized, and the project leader should be provided with sufficient time and opportunity to review the purposes, objectives, goals, and the scope and depth of the proposed assignment. The pre-project work may be characterized as a mutual tutorial process between project leader and client. Chapters Three and Four of the manual contain valuable information for these definitional purposes alone."

Certain other common steps in project methodology are also outlined and a number of suggested tables and matrices are included as Appendix C to aid the analyst in developing those specific illustrations that are particularly appropriate for a given project. Finally, Chapter Four provides some comments on the gathering and analysis of data, and the structure of recommendations flowing from project work in the pharmaceutical sector.

Chapter Five discusses specific problems encountered during distribution of pharmaceuticals to rural populations in LDCs.

Appendix A provides information about development planning for a pharmacy in a small hospital.

CHAPTER TWO

PHARMACEUTICAL SECTOR DYNAMICS

Definitional Issues

"Drugs," "pharmaceuticals," "medicines," "drug products," "pharmaceutical preparations," "medicinals" and similar terms all have one thing in common: They cannot be defined with universal objectivity and validity.

Legally, the definitions of these terms vary widely from country to country, and in most cases, the legislation is only concerned with one or two of the terms while ignoring the others; some countries have even avoided providing any legal definition in their laws governing these items.

The U.S. Federal Food, Drug, and Cosmetic Act (FD&C Act) provides the following definition of the word "drug": "The term "drug" means (a) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any articles specified in clause (a), (b), or (c); but does not include devices or their components, parts, or accessories."

Functionally, pharmaceutical or drug items serve purposes that cover an extraordinarily wide variety of professional disciplines and human endeavors, such as:

- Medical care (for example, in prevention, detection, diagnosis, therapy, and rehabilitation and cure of diseases and conditions).
- Economics (for example, as regards industry and trade, demand-supply phenomena).
- Sociology (for example, as affecting life styles, values, behavior).
- Politics (for example, concerning sociopolitical ideologies, notably social justice; foreign relations; national security).
- Religion (for example, regarding beliefs, practices, morality).
- Research (for example, in the biological, sociological, and psychological sciences).

Since these topics all cover large and often interconnected fields, it is not surprising that authors have rarely sought to give comprehensive treatment to this functional aspect of the many connotations associated with the terms drugs, pharmaceuticals, medicines, etc.

This manual shall not add to the confusion about definitions by developing its own versions. However, it may be concluded that the lack of an objective and universally valid definition contributes significantly to the dynamics that converge on the pharmaceutical sector, and that there is increasing preference for using the words "medicine" and "pharmaceutical" instead of "drug" in an effort to more clearly distinguish between the licit and illicit uses of these products.

At this point, it is appropriate to emphasize that this manual is concerned primarily with pharmaceutical specialties, i.e., products in finished dose-form, ready for use by professionals and patients. The section on "Product Assortment" in Chapter Three will assist the user of the manual in developing an operationally practical set of parameters to define the contexts in which terms such as "pharmaceuticals" are used.

National Pharmaceutical Policies

Few, if any, countries in the world have developed a comprehensive national pharmaceutical policy that can adequately respond to the varying demands that must be met under such an umbrella policy. Perhaps it is not possible to formulate the required guidelines in a cohesive package because of the dichotomous pressures applied by conflicting interest groups.

Consequently, policy decisions are often taken on an ad hoc basis in the basic areas that affect the pharmaceutical sector: Politics, economics, and health. Some of the issues and purposes underlying policy dilemmas in these areas are briefly summarized in the following paragraphs.

There are also numerous facets to the political aspects of developing a national pharmaceutical policy. The obvious stategic concerns--availability of adequate supplies for the nation's defense and police forces and for key members of government and business as well as for use to prevent, halt, and overcome epidemics--must be served and so must the basic needs of the general population. The "how to accomplish these objectives" require basic political decisions affecting the freedom of individuals (what are his rights and obligations in selecting, acquiring, and using a drug?), of professionals (what are the obligations and rights of various types of health professionals--physicians, pharmacists, nurses, midwives, etc--in using, prescribing, and dispensing drugs?), and of entrepreneurs (what constraints are placed on the freedom to make, import, distribute, and sell pharmaceuticals at a profit?).

Many of these political decisions cannot be taken without regard for international conventions (such as those on narcotics and psychotropics), international agreements (for example, regarding patents, trademarks, copyright in the private sector, and tariff, trade and investment in the public sector), or international political trends and realities.

Import substitution has been a fundamental development strategy in virtually all lesser developed countries (LDCs). The key objectives here are to save foreign exchange, build up a domestic industry, and provide employment for local labor. Export stimulation of manufactured or semi-processed goods is another primary development strategy. To work, these strategies must be supplemented with active and industry-supportive policies in technology transfer, in overall protection of the industries concerned from the vagaries of open competition, and in capitalization and financing. Superficially considered, the last stages of the pharmaceutical production chain fit eminently well into these strategies; in reality, however, the situation is often very different as discussed elsewhere in the manual.

Governments in LDCs usually cannot assign a very high priority to public health and medica care activities until a minimum level of economic development has been reached. For many LDCs, this minimum level will not be within reach for decades to come. Nevertheless in LDCs having a high and unacceptable population growth rate, this must receive special attention. Whatever resources can be spared for public health and medical care must therefore be allocated in the most efficient manner and in a way that provides immediately visible benefits to the population. Modern drug therapy undoubtedly meets these

requirements insofar as prevention and treatment of the standard contagious and infectious diseases are concerned. It is difficult to maintain government support for the usually ineffective and perhaps even unsafe indigenous medicines that, however, often are widely used and form an integral part of the nation's folklore, customs, and values.

The pharmaceutical industry must serve consumer demands and rising expectations with regard to better health. There is increasing acceptance of and even elaboration upon, the idealistic WHO definition "Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."

The desire for better health encompasses not only easy and inexpensive access to wholly safe and effective remedies, but also better understanding of the origins, actions, and proper use of pharmaceuticals, including associated risks and benefits.

The pharmaceutical industry must serve the needs of physicians and other health care professionals for factual and objective information about existing and new products. In addition, the industry is expected to provide new and better remedies to prevent, treat, and cure somatic and psychosomatic conditions, as well as symptoms arising from such social problems as alcoholism and narcotics addiction. The industry is also expected, through appropriate publication and funding policies, to serve the global scientific community and stimulate it to further discoveries about diseases and biological systems.

In LDCs, there is often a further source that affects the pharmaceutical sector, albeit often unnoticed. This source may be termed the voluntary assistance sphere. It is composed of numerous organizations--religious, philanthropic, mission-oriented groups--that often provide medical, health, family, and social services outside the framework of the country's own infrastructure. The dissemination of modern pharmaceutical products and information about them from voluntary assistance groups often adds significantly to the spectrum of good quality pharmaceutical services in the country at little or no immediate cost to the government.

International Pressure Forces

For decades, countries in the developed world and also in some developing countries--notably India--have paid special attention to the pharmaceutical sector. In the former, the focus of attention has been primarily on the health and medical aspects while in the latter countries, the primary focus has been on the economic aspects of the pharmaceutical industry.

Examples of the supranational entities and organizations now actively involved in the debate about pharmaceutical issues include many agencies of the United Nations (UN), the Organization for Economic Cooperation and Development (OECD), the European Economic Community (EEC), the Central Treaty Organization (CENTO), the Andean Common Market (ANCOM), the International Federation of Chemical and General Workers' Unions (ICF), the International Labor Organization (ILO), the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), and the World Federation of Proprietary Medicine Manufacturers (WFPMM).

Currently, upwards of a dozen agencies and commissions operating under the UN umbrella are involved with pharmaceutical affairs, and an interagency Task Force has been established to develop common basic policies. So far, no policy statements have appeared from the Task Force, but an outline of its plans is discussed in the international pharmaceutical trade journal, SCRIP (7/2/77).

While WHO advocates the laudable aim that national drug policies should give priority to the country's health needs, there is much evidence that

governments--especially in those countries which have fostered a domestic pharmaceutical industry with sizeable commercial interests--are actually placing increasing emphasis on the economic needs of their pharmaceutical industry.

The reason is clear if one considers the global size of the pharmaceutical market--see Table 1 for some pertinent estimates--and the potentials for economic growth and technological development in the pharmaceutical business. In 1985, the global business in pharmaceuticals is projected to considerably exceed U.S. $100,000 million ($100 billion), up from an estimated $37,500 million ($37.5 billion) in 1975. These values are expressed in terms of manufacturer's prices; distribution margins, taxes, and duties roughly account for similar amounts. Thus, at retail prices the world market for pharmaceutical specialties was worth about U.S. $75,000 million ($75 billion) in 1975.

TABLE 1

ESTIMATED GLOBAL PURCHASES OF HUMAN PHARMACEUTICALS
BY MAJOR WORLD REGION AND COUNTRY, 1975
(U.S. Dollars, Manufacturers' Prices)

	Regional Total (millions)	Country Total (millions)	Per Capita Averages
World Total	$37,500		$ 9.60
North America (incl. Caribbean)	9,000		
U.S.A.		$7,500	35.05
Mexico		800	13.70
South America	2,400		
Brazil		1,000	9.30
Argentina		600	26.10
Western Europe	12,750		
France		2,750	51.90
West Germany		3,350	53.35
U.K.		1,100	19.50
Sweden		300	36.60
Eastern Europe	5,250		
USSR		3,500	13.70
Asia	6,800		
Japan		4,250	38.45
India		450	0.75
Africa	825		
South Africa		325	11.10
Nigeria		75	1.20
Oceania	475		
Australia		400	29.65

Note: Because of definitional uncertainties, lack of comparable statistics, possible double counting, currency fluctuations, and differences in inflation rates, the data in this table reflect rough estimates only.

Source: "Pharmaceutical Industry Dynamics and Outlook to 1985," Stanford Research Institute, 1976.

The Pharmaceutical Industry

The pharmaceutical industry is not a single industry. It covers instead a highly heterogeneous range of industrial and trade activities, carried out by companies that have widely diversified raw material and dose-form operations in human ethical pharmaceuticals, proprietaries, veterinary and animal health products, diagnostic indicators, and reagents, sutures, dressings, and other types of medical supplies, therapeutic nutritional products, and products for ordinary, nontherapeutic human health care.

In short, references to "the pharmaceutical industry" are as imprecise and meaningless as are references to "pharmaceuticals," "drugs," "medicines," etc.

The listing below identified the leading (in terms of 1976 annual sales) pharmaceutical companies by name and location of corporate headquarters. The sequence in which the companies is listed gives a rough indication of their ranking by pharmaceutical sales volume within countries, but it does not indicate the size of their international operations; in some instances, these are very large (the Swiss firms) while in others they are very small (the Japanese firms).

Further, it should be noted that because of acquisitions in many countries, many of these large companies operate under a variety of corporate names. For example, Johnson & Johnson is the corporate parent of a wide range of pharmaceutical companies, including McNeil and Ortho in the United States, Janssen in Belgium, and Cilag-Chemie in West Germany; each of these firms operate under their own names in a multitude of individual country markets.

Name of Corporate Parent	Location of World Headquarters
American Home Products	United States
Merck & Co.	United States
Warner-Lambert	United States
Eli Lilly	United States
Bristol-Myers	United States
Pfizer	United States
Schering Plough	United States
Sterling Drug	United States
Upjohn	United States
Squibb	United States
Johnson & Johnson	United States
SmithKline	United States
American Cyanimid	United States
Dow Chemical	United States
G.D. Searle	United States
Abbott	United States
Richardson-Merrell	United States
Syntex	United States
A.H. Robins	United States
Rorer	United States
Hoechst	West Germany
Bayer	West Germany
Boehringer-Ingelheim	West Germany
Schering A.G.	West Germany
Boehringer-Mannheim	West Germany

Name of Corporate Parent	Location of World Headquarters
E. Merck (Darmstadt)	West Germany
BASF	West Germany
A. Natterman	West Germany
Hoffmann-La Roche	Switzerland
Ciba-Geigy	Switzerland
Sandoz	Switzerland
Beecham	United Kingdom
ICI	United Kingdom
Wellcome	United Kingdom
Glaxo	United Kingdom
Boots	United Kingdom
Rhone-Poulenc	France
Elf-Acquitaine	France
CM Industries	France
Pechiny-Ughine-Kuhlmann	France
Servier	France
Montedison	Italy
Takeda	Japan
Shionogi	Japan
Sankyo	Japan
Fujisawa	Japan
Eisai	Japan
Taisho	Japan
Daiichi	Japan
Tanabe	Japan
Banyu	Japan
Yamanouchi	Japan
AKZP	Holland
Gist-Brocades	Holland
Astra	Sweden
Lundbeck	Denmark
Leo	Denmark

Each of these corporations is extremely difficult to characterize because of its numerous activities, its particular strengths and weaknesses as perceived by individual analysts, and its often unclear past record. Nevertheless, the tendency among industry observers, and also increasingly among government officials, is to group all pharmaceutical corporations into two broad categories: Those that are research intensive, and those that are not.

As shown in Table 2, the pharmaceutical industry probably occupies a unique position among business organizations in terms of the scope and depth of participation in international markets by individual pharmaceutical companies. The data in the table expresses the number of different countries in which a given company operates; thus, in cases where a company has multiple activities of a particular type (for example, three own marketing forces) in one country these are only counted as one.

In the LDCs there is a proliferation of smaller multinational companies, some of which do not have any or sometimes only insignificant sales in their own countries.

TABLE 2

PHARMACEUTICAL COUNTRY OPERATIONS OF FIRST TIER COMPANIES, BY TYPE AND NUMBER, 1974

Company	Marketing Organization		Production Capacity		Research Facilities	
	Own	Agent	Manufacturing	Packaging	Major	Minor
Hoffmann-La Roche	32	76	16	30	6	21
Hoechst*	130	0	14	37	7	2
Ciba-Geigy	50	10	14	41	5	15
American Home Products	80	50	5	25	3	10
Merck & Co.	60	100	28	28	2	8
Sandoz	46	61	8	22	3	5
Bayer	48	45	12	19	3	7
Warner Lambert	50	90	10	35	3	10
Eli Lilly	28	117	5	12	2	13
Pfizer+	75	75	10	45	3	10
Bristol-Myers	60	55	5	20	4	10
Boehringer-Ingelheim+	46	40	5	10	1	5
Takeda	12	40	4	3	1	1
Schering-Plough+	60	60	5	25	2	6

Note: "Pharmaceutical" includes only ethical and proprietary specialties, in dose form, for human use; proprietary products included are only those with a recognized therapeutic activity.

*Excluding Roussel-Uclaf

+Data estimated by SRI

Source: "Pharmaceutical Industry Dynamics and Outlook to 1985," Stanford Research Institute, 1976

Pharmaceutical Supply Systems

There are a multitude of activities and entities that can be viewed as components of a pharmaceutical supply system, but they do not lend themselves to logical compartmentalization into a single, cohesive system. Chapter Four of the manual describes some key functional, evaluative, and motivational aspects of a conceptualized, comprehensive pharmaceutical supply system. In this section of the manual, however, certain elements will be aggregated differently and briefly described as individual subsystems. Some of these subsystems integrate with, complement, or compete with others, but none operate in isolation. This lack of independent variables along with the multitude of dependent variables present the chief obstacles to efficient management of the pharmaceutical sector.

The literature contains few references to "pharmaceutical supply systems" and even fewer attempts at defining the components and configurations of such systems. Recently, WHO has addressed itself to this deficiency and in building on work by Stanford Research Institute, notably the study, Pharmaceutical Industry Dynamics and Outlook to 1985 (1976), Dr. H. Nakajima, Chief, Drug Policies and Management, WHO Headquarters, Geneva defined and discussed a pharmaceutical supply system in a paper, National Drug Policies and Management, delivered to the 28th Session of the WHO Regional Committee in Tokyo on September 9, 1977.

The technical and administrative components of a fully developed system accordingly are as follows:

- Drug research and development.
- Drug legislation and regulatory control.
- Product selection.
- Quality assurance.
- Procurement from multiple sources of supply.
- Local production.
- Distribution.
- Control of drug prices.
- Drug information, utilization surveillance, and training of health workers.
- Utilization of locally available natural resources for health care.
- Self medication.

The efficiency of a pharmaceutical supply system--considered from only the public health/medical care viewpoint--needs to be judged against one criterion only:

> Does the system consistently ensure equitable and ready patient/consumer access to and use of the right product at the right time at a reasonable price?

There is probably not a single country in the world that can uniquivocably meet this test--even if one could ever agree on the definitional issues inherent in the question.

Some specific subsystems that operate within the pharmaceutical sector are briefly considered in the following pages.

Physical product systems include these main elements: Import, Manufacturing, Wholesale Distribution, Institutional Distribution, and Retail Distribution. Nations have organized their physical product systems according to various basic models. Some that are particularly applicable to LDCs are summarized below.

Sri Lanka. A State Pharmaceuticals Corporation (SPC) under the Ministry of Industry and Scientific Affairs has a monopoly on import (and export) of pharmaceuticals and on purchase of domestically produced pharmaceuticals. SPC supplies both the private sector and the public sector entities that handle further distribution. SPC also manufacturers, processes, stocks, packages, and repackages pharmaceuticals. SPC is reported to be saving Sri Lanka considerable amounts of foreign exchange on both pharmaceutical specialties (finished pharmaceuticals in dose-form) and raw materials for local production into specialties without significant adverse effects on the quality, quantity, and availability of pharmaceuticals to the population. There is, however, evidence of dissatisfaction with the system among private businessmen and medical professionals because of a drastic curtailment of the product assortment, changes in the sources of supply, and arbitrary actions vis-a-vis private pharmaceutical manufacturers in the country. Additional information about the "Sri Lanka" model is provided elsewhere in this manual.

Peru. A Permanent Commission on Basic Drugs (the Commission) under the Minister of Health is charged with 25 specific functions, including determination of the product assortment under the Basic Drugs Program; control of the acquisition, importation, manufacturing/processing, and distribution of drugs under the program; and overall program oversight, development and promotion. About 300 drugs are covered by the program.

As in the case of Sri Lanka, the Peruvian program is reported to have resulted in lowering the direct cost of purchasing pharmaceuticals. Adverse commentary about the program also mirror those in Sri Lanka. Further details on the Commission and the entire program is available from document No. CD23/29, dated October 1, 1975, issued in connection with the XXVII Regional Committee Meeting of the WHO in Washington, D.C., and from a review of the program in SCRIP (11/8/73).

Zaire. There is a sharp distinction between the public and private sectors in Zaire. The former is by far the smaller in terms of volume and also its organization is very weak. The Depot Central de Medicaments Pharmaceutique (DCMP) is charged with importing and distributing pharmaceuticals for the public sector, while one of the large pharmaceutical multinational corporations (NMC), Warner-Lambert is the main importer, domestic manufacturer, and distributor to the private sector; the company handles, in addition to its own product lines, the Zairian business as exclusive agent for another 45 European and American pharmaceutical companies. Some additional information on the pharmaceutical supply system in Zaire is available from Volume XIV: Zaire in the Syncrisis series published by the Office of International Health in the U.S. Department of Health, Education, and Welfare.

These three country examples are representative of the typical patterns of pharmaceutical supply systems one finds in the LDCs today. Some of their main characteristics are:

- Varying degrees of direct government participation in the acquisition and distribution of pharmaceuticals.
- Emphasis on government participation in institutional distribution of pharmaceuticals in the public sector.
- Relatively little involvement by the government in manufacturing and retail distribution.

Few countries operate a pharmaceutical supply system that is controlled and operated by the government in all facets (such as Burma) or that is virtually devoid of any government participation in the physical product system at all (such as South Korea).

A viable pharmaceutical supply system must feature an appropriate mechanism to inform, educate, and convince users of the merits and drawbacks of modern pharmaceuticals; otherwise, the system will quickly entail inappropriate utilization of these remedies.

Another aspect of the use of pharmaceuticals is that in palliative drug therapy--as opposed to prevention and cure--the drug substances themselves may often only achieve their desired action when the patient is convinced beforehand of their beneficial influence on his health and well-being. Under these circumstances, it is not surprising that the pharmaceutical industry considers the communicative component of its "product" an integral part which cannot be disassociated from the physical component (the pharmaceutical specialty itself).

In the LDCs the physician, because of his stature and function in the health care system, becomes the key figure in the communications dilemma. If trained outside the country, particularly if he is a foreigner temporarily practicing in the country, the physician is probably already accustomed to relying on the pharmaceutical industry for his continuing medical education. If trained

within the country, the physician presumably feels a particularly great professional need to discuss drug therapy with representatives of the foreign pharmaceutical industry.

Physicians throughout the world have a need for continuing education, a need that discourages them from seeking to establish themselves or accept more than short-term assignments in professionally and socially isolated areas. Because of their often larger supervisory responsibilities for other health workers, LDC physicians are likely to have a broad need for new information. Many of these points also apply to pharmacists.

Throughout the world, the importance of an appropriate communications system is being stressed. In the Soviet Union, misuse of pharmaceuticals is now being blamed on the lack of industry promotion for its products and the Russian drug makers are being instructed to step up their promotional campaign. On the other side of the spectrum, in Sweden--where pharmaceutical promotion has been tightly controlled for years--the government has moved vigorously to further curtail the amount and dissemination, edit the content, channel the flow through special therapeutic committees, and directly participate in the distribution of information pertaining to the use of pharmaceuticals.

Some main concerns that must be addressed in a communications system include:

- Education of professionals, paraprofessionals, and consumers.
- How to originate information.
- What information should be provided to which audience.
- Methods and channels of dissemination.
- Quality control measures.
- Continuing education.
- Feedback mechanisms.
- Cost parameters.

In this context, it should be emphasized that in countries where governments have attempted to drastically reorganize the pharmaceutical supply system, failures have often resulted from lack of attention to the importance of the communications system.

Before the pharmaceutical industry is too hastily indicted for "selling pharmaceuticals like soap" and before country governments are equally hastily accused of regulatory irresponsibility one needs to examine carefully the yardsticks or morality one wishes to apply.

In this connection, it is pertinent to quote some paragraphs from a report by the United Nations Institute for Training and Research, Technology Transfer in the Pharmaceutical Industry (1971): "The multinational firms' efforts in the LDCs paralleled what they had done in the United States. When attempting to enter LDC markets, firms quickly discovered that physicians' knowledge of pharmacology was by and large extremely poor, and that much of good medical practice in general was lacking. This meant that wide adoption of new drugs in the LDCs could not come about unless there was a significant amount of physician education. Most of the LDCs' had little in the way of medical-scientific establishment, and little facility for dissemination of information through scientific channels.

Therefore, virtually the entire task of pharmacological education fell to the multinational firms, and they attacked the task using the detailing and advertising tools they were learning to use so effectively in the advanced countries. Once again, their efforts were self-serving in that the desired end point of individual firms' efforts was sales of their own products. But, once again, the results of these firms' efforts had a great deal of social

utility. It is not at all unreasonable to believe that without the educational efforts of the multinational firm, the state of medical practice would not have advanced nearly as much in the developing countries."

Thus, any changes in current promotional/informational systems are not made easily and need to be adequately financed to make the desired impact.

Another key element of a pharmaceutical supply system is the method by which pharmaceutical products and services are paid for. In a report recently submitted to the Mission in Seoul of the U. S. Agency for International Development, "Financing Health Care Services in Korea," the following six basic methods are: Direct purchase by consumers, Charity donations, Commercial insurance, Industrial support, Social insurance, and General revenue support from government taxes.

The report points out that each method has different policy implications and that funds derived from many sources tend to result in wide dispersion of responsibilities and authority. The trend internationally is for the first three methods to assume less importance, while the latter three methods are becoming more important--a development which is attributed to societal development goals.

In the LDCs, the typical pattern is clear; the financially strongest segments of the population pay for their pharmaceutical needs out-of-pocket either wholly or in part, or obtain needed products and services gratis as an employee benefit from their employers (including government agencies). Commercial insurance programs play a very minor role, and social insurance systems are generally in their infancy both in terms of the pharmaceutical benefits they provide and in terms of the number of people who are covered and have ready access to service providers.

Irrespective of its method of financing, a pharmaceutical benefits scheme must be considered in context with not only the country's health care system but also in context with the entire social benefits scheme (including pension, unemployment, illness, maternity, and child support systems). It must also consider indigenous customs. Without such an integrated and cross-sectorial approach, the pharmaceutical scheme is likely to be subject to abuse or underutilization.

For example, in certain Middle Eastern countries, women are reported to often meet for social purposes at government operated clinics under the pretext of some ailment and to simply discard the medications handed them after they leave the clinic. In Korea, by contrast, a recently introduced benefits scheme for the poor funded by the government remains virtually unused, reportedly because indigenous medicine is not included among the covered services.

When measured as just one item among others in the average household budget, consumer expenditures on pharmaceuticals are typically low throughout the world. Even in the LDCs, personal consumption expenditures on items such as cigarettes, coffee, and entertainment on the average exceed the amount of money spent on pharmaceuticals by considerable margins. This pattern even holds true in countries where the pharmaceutical component of national health care expenditures exceed 50% of the total. However, disease and sickness patterns do not fall evenly among a country's population nor do the financial burden of coinsurance and patient copayment schemes. Inevitably, the poorest members of society are hardest hit financially.

Mixed public and private insurance systems, such as in Japan, tend to saddle the public sector with the poorest risks and lead to increasingly large fiscal deficits for the publicly financed programs while the private insurance system prospers.

Sensitive political and economic dilemmas are involved in answers to questions such as: Who should be covered? What should be covered? For how long should coverage extend? What should be the cost of coverage? What is an appropriate cost and utilization control mechanism? Also, because of inadequate resources to finance and administer a comprehensive pharmaceutical benefits scheme, few LDCs have felt ready to address the complexities of a formal insurance mechanism. Some have, however, made initial moves by establishing insurance systems for easily definable population segments (for example, civil servants, employees of large firms) with the objective of expanding and modifying the systems as the resource availability improves.

Generally, pharmaceuticals are traded like ordinary consumer commodities in LDCs and are consequently available in an array of outlets where their handling, storage, and dispensing is often inappropriate. However, without such lenient distribution systems, patient access to pharmaceutical products and services would be severly encumbered. Because of international agreements, narcotics and psychotropics are subject to special limitations, and patients can normally obtain them only on a doctor's prescription.

There are two main components in a patient access system: retail contact points and institutional contact points. In LDCs, the distinction between them is blurred because pharmacy (dispensing) is often not separated from medicine (diagnosis and prescription). Thus, pharmacists will often act as the primary health care worker and physicians will frequently carry stocks of pharmaceuticals; typically, both are entrepreneurs first and medical professionals second.

In many LDCs, particularly in areas away from the main urban centers, pharmaceuticals are available from nondegreed health workers (midwives, traditional practitioners, nurses aids, etc.) or ordinary storekeepers who may or may not have a special license from the authorities to handle certain types of pharmaceuticals.

Private, for-profit outlets for pharmaceuticals, especially in urban areas of LDCs, often compete with free public clinics. In many countries, for example, physicians are required to work a certain number of hours in government-run clinics or hospitals, but they are allowed to have their own separate private clinics where they treat patients who can afford it. Often, the physician in private practice and the pharmacist/drug seller will carry products different from those available free from the government facility. Obviously, this leads easily to the conclusion on the part of consumers that for-pay private medicine is superior to gratis public medicine. Consulting a pharmacist is less costly than visiting a physician in private practice, and pharmacists have therefore obtained a strong franchise in the health care market in many localities throughout the developing world. Since the majority of ailments and sicknesses are fairly standard, the pharmacist needs only little diagnostic training in order to decide on the right pharmaceutical product for the patient's condition. Complications as a result of erroneous diagnosis and associated inappropriate pharmaceutical care are probably less frequent than complications associated with the proper diagnosis but less than appropriate drug therapy; in the latter case, the assumption is that the pharmacist/drug seller when out of stock of the proper drug will furnish a less appropriate product to the patient.

The overlapping roles of physicians, pharmacists and other individual retail distributors of pharmaceuticals lead to professional conflicts which require political solutions regarding the professional prerogatives of the various classes of health workers. This, naturally, provides a further dynamic element in a country's pharmaceutical supply system.

Finally, among these examples of pharmaceutical supply subsystems, it is warranted to look at a subsystem that may be considered from a sector viewpoint. Three major sectors are involved operationally: the government sector, the private, for-profit sector, the private, not-for-profit sector.

The first sector consists of at least two parts, that under the administration of the Ministry of Health and that under the Ministry of Defense, but often there are many more ministries with administrative influence on the acquition and distribution of pharmaceuticals, for example, the Ministry of Home Affairs (police force, civil servants are among its typical "clients"), and the Ministry of Industry (large industrial, mining, drilling, agricultural operations, occasionally state owned, are among those included). Pharmaceutical requirements of the various governmental entities are reported to be covered through autonomous purchase and supply mechanisms without regard for other supply systems within the public sector.

Different ministries frequently operate independently, and coordination among them with regard to their pharmaceutical requirements is difficult, if not impossible to achieve--especially in LDCs where the Ministry of Health is always among the weakest and least influential ministries, albeit the largest government drug purchaser and distributor.

The private-for-profit sector consists of several entities with distinctly different functions and objectives as outlined in the earlier section, "Physical Product Systems." However, because of a low stage of economic development, small populations, or for other reasons the functions of several entities are frequently performed by a single corporation. In addition to segmenting this sector into parts comprising importers/distributors; manufacturers; and retailers, it is also pertinent to distinguish between domestic and foreign capital interests because their objectives and strategies usually vary markedly.

The private not-for-profit sector consists of a wide array of different voluntary agencies and relief organizations. Most of these are national in their origin and usually provide their facilities in the LDCs with medical care and supplies, including pharmaceuticals, according to their home-country standards; religious and philanthropic entities are typical examples. An organization located in New York City, Technical Assistance Information Clearing House of the American Council of Voluntary Agencies for Foreign Service, Inc., maintains comprehensive data on U.S. nonprofit organizations active in development assistance programs. In most LDCs, there is little, if any, communication and cooperation among these types of organizations, and this is especially true where there are competing interests among similar types of different national or religious groups.

In addition to these three major parts of such a sector subsystem as discussed here, there may also be others that are important. Examples include pharmaceutical services provided as an employee benefit by domestic or foreign, for-profit corporations through a company clinic or hospital, and supranational relief organizations such as UNICEF (United Nations Children's Fund) and UNESCO (United Nations Educational, Scientific and Cultural Organization).

Lack of coordination among the various sectors, and even lack of basic knowledge of their pharmaceutical services, are among the primary causes for fragmented pharmaceutical supply systems in the LDCs.

Government Intervention

So far, this chapter on Pharmaceutical Sector Dynamics has dealt with selected aspects of the factors and forces that cause continuous change within the sector under three major headings; Definitional Issues, National Pharmaceutical Policies, and Pharmaceutical Supply Systems. In this section, a fourth major dynamic element--Government Intervention-- will be overviewed.

The former Chief Counsel of the U.S. Food & Drug Administration (FDA) in a paper entitled, Who Regulates the Regulator While the Regulator Regulates. (Peter Hutt, 1976) provides the following rationale for government intervention: "The rationale customarily given for government regulation of consumer products, and now almost universally accepted, is that, in a complex society, individual consumers can no longer protect their own interests and the government must therefore do it for them. Implicit in this well-recognized principle is that there is something against which the public in fact does need protection. It means that, without this protection, consumer products would be marketed without adequate assurance of safety and, where appropriate, effectiveness.

If one examines historical developments in the field of government regulation, it is readily apparent that this implicit assumption has in fact been the activating force behind all federal legislation enacted to regulate the safety and effectiveness of consumer products. The history of the increasing government regulation in this field is the history of the perceived failure of business to regulate itself in a way sufficient to satisfy the public's felt needs. Time and again, Congress has acted in response to what it believed to be a demonstrated danger."

While there is little doubt that the above quotes touch upon the essence of any rationale that has guided the stewards of society throughout the world in setting regulatory boundaries for entrepreneurship in the pharmaceutical field, there are also other reasons. Chief among these are varied motives by politicians, bureaucrats, medical professionals, and businessmen, as already discussed previously.

In the LDCs where all resources are scarce and those in the entire health sector particularly so, and where the educational level of consumers is low--especially in the rural areas--these is a greater emphasis on economic than on health and medical rationales. However, since LDCs tend to adopt rather uncritically the pharmaceutical, medical, and food legislation as well as the medical practices of developed countries, the trade-offs between the economic and medical rationales for government intervention become more complex and politically sensitive. This will be discussed further in a subsequent section of this chapter.

The focus of government intervention is also multifaceted, and because of the economic laws governing all commercial activity, regulatory intentions often cannot be implemented as planned. This will become abundantly clear in Chapter Four. It may be possible to narrow the scope of the regulatory focus by exploring the concepts that underlie most laws and regulations in the pharmaceutical field. These concepts can be reduced to the following four:

Quality of products and services: This encompasses the safety, efficacy, and proper labeling--which includes claims, directions for use, and warnings--of products; the standards of the professional and paraprofessional manpower; the physical conditions of and the practices in facilities; and much more as discussed elsewhere in the manual.

Costs of products and services: This includes considerations of equitable access and availability for those with a "legitimate" medical need for not only drug therapy but also medical and health care. Under this concept, prevention of asocial profiteering by the suppliers is also being pursued.

Need for products and services: This entails judgments about adequacy and desirability of particular pharmaceutical interventions in the human condition (somatic and psychosomatic diseases, other states of being less than "well"). It also entails judgments about the level of freedom a medical professional should have in practicing his profession and trade, and a patient's freedom to care for himself as he sees fit.

Use of products and services: This deals with the rights and duties of patients, professionals, paraprofessionals and others who are instrumental in a human being's use of pharmaceuticals.

It is clear that in dealing with these concepts legislators, regulators, and judges must deal with basic sociopolitical and politico-philsophical issues-such as human rights, the nature of an individual's freedom in society, and private property rights. These concepts are embodied in regulatory actions with more specific focus. The listing below shows some examples of the spectrum of these foci and their scope:

Spectrum of Foci	Scope of Foci
Products	Ethicals, proprietaries, biologicals, narcotics; specific therapeutic categories, classes and subclasses; specific pharmaceutical compounds; specific pharmaceutical specialties, single entities and combinations; physical characteristics (size, weight, volume, shelf life, storage requirements).
Facilities	Retail outlets, institutions, plants, laboratories, warehouses, storerooms.
Sectors	Private for-profit, public, voluntary assistance; urban, rural.
Entrepreneurs	Manufacturers, importers, distributors, retailers.
Professionals el alia	Physicians, pharmacists, dentists, nurses, midwives, indigenous practitioners, other assistants.
Financing	Compulsory versus voluntary insurance; public versus private insurance; private, out-of-pocket pay.
Users and Patients	Infants, children, adults, geriatrics, males, females, pregnant women, inpatients, outpatients, literates, illiterates.
Diseases and Conditions	Acute, chronic; infectious, parasitic; congenital; environmental, sanitary, dietary; "minor," "major."
Treatment	Prevention, therapy.

With all these variables, it is not surprising that regulatory side effects are frequent, meaning that a regulation intended to produce one effect in one area of concern often entails another, perhaps undesirable effect in another area.

The methods by which a government chooses to implement its pharmaceutical policies vary greatly among nations and reflect basic strengths and weaknesses in their societal structure. Indications are that societies with a great deal of trust among its members tend to write broad laws leaving a fairly wide scope for the administrative implementation by bureaucrats. Further, constitutional differences among countries can explain differences in regulatory approaches.

From a public sector viewpoint, distinction can be made among three methods of intervention in pharmaceutical supply systems: Indirect intervention; Regulatory intervention; Participatory intervention. While a particular government relies more on one of these methods than the two others, virtually all governments employ a mix of these approaches.

Indirect intervention is accomplished by granting special privileges to medical professionals and paraprofessionals and businessmen. For example, the right to issue prescriptions, granting protected competitive environments, limiting the "production" of specialized manpower, and restricting the sources of supply and the distribution network. The expectation or condition is that these segments of society establish codes of conduct, enforce them, and pursue policies in tune with the government's overall objective through their various associations.

Regulatory intervention is directly focused on components of the pharmaceutical supply and undertaken through an array of specific tools, some of which are discussed later.

What is here termed participatory intervention implies direct participation by a government entity in the production, procurement, distribution and/or marketing of pharmaceuticals. This method has been and continues to be attempted throughout the world, and preferences for this method shift in accordance with the political winds prevailing at a given time. The experience of government owned and operated plants and factories in the pharmaceutical business has generally been negative (Egypt, Indonesia, India, and Burma all come to mind in this connection) where these enterprises have not been run as ordinary for-profit enterprises. State monopolies in the manufacturing sector have not proven effective remedies because of the particular product mix needed by a pharmaceutical manufacturing operation and because of the constant pressures from new technologies developed aborad. Direct government participation in the procurement and distribution mechanism appears to have been somewhat more successful (Norway, Syria, Iraq, Sri Lanka).

Speaking in general terms it would appear that direct government participation in the pharmaceutical supply system offer few, if any, advantages over private sector operations, and that the issue of public vs. private ownership of the facilities and management of the system has little bearing on the "efficiency" of the system.

Selected Regulatory Tools and Issues

As mentioned earlier, there is a wide array of specific regulatory tools that can be applied in an effort to achieve the optimal characteristics of the kind of a pharmaceutical supply system a society desires for its members. In considering merely the physical product systems, it is convenient to group these tools into two categories: those that can be applied prior to market entry, and those that can be applied after market entry. Market entry "covers products, services, firms, personnel, etc., and the tools are essentially various kinds of licensing and certification schemes.

In the developed countries, there is now a shift to increasing attention to the post-marketing types of controls. Simultaneously, there may be some lessening of the controls associated with premarket clearance. By contrast, LDCs devote virtually all their efforts to using tools that regulate market entry, and LDCs are far from having reached the regulatory sophistication that characterize "western" countries.

A summary discussion of a few key regulatory tools is provided in the following paragraphs.

Product Registration: In the developed countries, led by Sweden, the United States, Canada, France, the United Kingdom, and Japan, a complex maze of laboratory tests and clinical trials set the technical criteria for the registrability of new pharmaceuticals. Despite significant differences among the regulatory approaches to product registration in the developed countries, in all cases the burden of proof is on the company that petitions for marketing approval. In some countries, government-employed experts decide on a new product's merits, in other countries, experts drawn from academic establishments evaluate the evidence.

The LDCs lack adequate resources (manpower, facilities, know-how) to evaluate similarly extensive documentation, and depending on their regulatory sophistication in the food and drug field will accept varying kinds of proof that a product is safe, effective, and properly labeled These kinds range from the so-called Free Sale Certificate--a document prepared by the foreign supplier and certified by the pharmaceutical registration authorities in the exporting country which state that the product concerned is "freely" available in the country of origin--to a more comprehensive package of lay, professional, and technical literature and documentation.

In an attempt to guard against possibly erroneous assumptions about safety and efficacy trials carried out elsewhere; to further the technology transfer process; and to lay the foundation for domestic pharmaceutical research, some developing countries are now demanding that suppliers carry out certain clinical and even laboratory testing at designated facilities within the country. Such demands are, of course, only seriously considered by the manufacturer where the supplier's potential sales and profits and corporate strategies so warrant.

Apart from the technical requirements for product registration, most countries also have economic criteria that must be met before a product is accepted for registration. For example, in one situation, the product may meet a medical need, but be considered too expensive; and the reverse may happen. Underlying both the technical and economic criteria is the qualitative assessment of "need."

The preceding comments on product registration have dealt with modern pharmaceuticals only. Since many LDCs continue to depend on indigenous remedies for the major part of their needs for medicine, it should be pointed out that indigenous remedies are usually not subjected to any registration requirements.

The lack of supervision by the authorities over these "natural medicines" may be a considerable health hazard since concoctions analyzed both in LDCs and in the developed world have regularly been found to contain potent modern drug substances such as various types of antibiotics, steroids, aminopyrine, and phenylbutazone.

Import controls: these are among the most widely used and most effective in all LDCs. There are numerous different systems in operation throughout the world, a description of which goes beyond the scope of this manual.

These controls, such as customs duties, customs clearance procedures, taxes, and general business regulations--are often imposed for reasons that have nothing at all to do with the adequacy and efficiency of the country's pharmaceutical supply system; however, they cannot only interfere with, but also completely frustrate and virtually nullify the plans and efforts of those government officials who are charged with guiding and supervising the country's pharmaceutical sector.

Industrial development policies aiming at import substitution provide government regulators with further tools to control the pharmaceutical sector.

Superficially considered, many pharmaceutical products would seem to lend themselves ideally to local production, but in reality, a range of criteria need to be established and accommodated before an import substitution policy is implemented for pharmaceuticals. Further details on this is given in Chapter Four, see "Domestic Production."

Product Exclusivity: The major tools available to government regulators in this area concern patent, trademark, and copyright protection. Some LDCs disallow any form of patents, and most of the 80-odd countries--both developed and developing--that are signatories to the Paris Convention for the Protection of Industrial Property restrict the scope of the patentability of pharmaceuticals. Basically, there are three types of patents: process, substance, and product; the latter grants the most complete exclusivity while the former provides the least. Patent periods vary widely, from less than 10 years in some countries to 20 years in others, with the shorter periods generally being found in LDCs and the longer in the technologically advanced countries.

The trademark issue in the pharmaceutical sector has also been the focus of much controversy for decades, and in more recent years, has been associated with the demand in virtually all countries for "generic" pharmaceuticals. Supplying pharmaceuticals--at least a major portion of the ethical products--under their common (generic) name is thought to increase substitutability among similar, identical, related or "me-too" drugs, and thus--through increased competition--lead to lower prices. There is a rich body of literature on this topic from which one may broadly conclude that without a strong system--operated or supervised by the government--to guarantee "generic" product quality and to police the supply of pharmaceuticals, public health and medical calamities might occur.

Nevertheless, many LDC governments feel strongly that the "generic" approach offers great potentials--and so do some groups in the developed world, notably in the United States--and two of Pakistan's neightbors have not been discouraged by that country's experience. Afghanistan has recently enacted comprehensive legislation in this field, and Indian government spokesmen have stated that a policy of gradual and selective switching to generic names will be pursued in that country.

Good Manufacturing Practices (GMP): To ensure a minimum quality level for pharmaceuticals to guard against the distribution of poor quality products--and presumably to discourage the less scrupulous manufacturers from selling (or donating) undergrade pharmaceuticals to LDCs with weak pharmaceutical monitoring systems--WHO has taken the initiative to establish minimum standards for the manufacture and quality control of drugs. A scheme has been established to certify the quality of pharmaceutical products moving in international commerce. Both topics (manufacture and quality) are covered in issue No. 367 in WHO's Technical Report Series, entitled, WHO Expert Committee on Specifications for Pharmaceutical Preparations: Twenty-fifth Report (1975). The certification scheme ties in with the free sale certificate mentioned earlier (see "Product Registration"). The GMP-specifications are generally considerably below the standards which already apply in many developed countries, and will appear even more moderate when impending new GMP regulations are issued by FDA in the United States, probably during 1978.

Enforcement of GMP regulations provides government officials with tremendoubly potent regulatory tools. Implicit in this is, of course, that the government employs a sufficient cadre of qualified factory inspectors.

Product Recall: An effective pharmaceutical supply system needs a mechanism whereby dangerous, unsafe, ineffective or otherwise inappropriate pharmaceuticals

can be removed quickly from the marketplace. This mechanism is often absent in the LDCs because of inadequate surveillance and monitoring systems.

Costs/Benefits Assessments

No literature is known to exist on the subject of the costs versus the benefits of government intervention in the pharmaceutical sector in LDCs. There are vague notions, however, that the overall benefits derived from an adequate and rational pharmaceutical supply system in terms of alleviation of pain and suffering, in terms of lives saved, in terms of increased life spans, and in terms of increased labor productivity, easily outweigh the costs of the pharmaceutical products themselves (including their nonchemical values such as information, hope, etc.), the costs of paying the salaries of those who operate and oversee the pharmaceutical supply system, and the much higher societal costs and burdens of interfering with what Darwin called the "natural selection" process in an already impoverished country.

In the developed world, in recent years, more attention has been devoted to measuring the value to society of various social investments, including those in health and, more specifically, in pharmaceuticals and drug therapy.

Policy Formulation and Execution

Some of the pressure forces that combine to shape national pharmaceutical policies have been outlined in an earlier section of this chapter, and the obvious implication has been made that the centers for actionable policy formulation and actual policy implementation are found within different power groups in each country. Efforts to coordinate the activities of these groups appear to be most successful in countries with rather small, homogenous populations or in countries with strong executive branches of government. By contrast, societies that seek equilibrium among the legislative, executive, and judicial branches of government tend to experience the greatest difficulties in setting and carrying out national pharmaceutical policies. The real power of lower and middle level bureaucrats is often said to be a particular problem for innovative policy makers in LDCs.

The costs of operating a central drug control agency are considerable. In its Ten-Year Health Plan for the Americas--Final Report of the III Special Meeting of Ministers of Health of the Americas (1973), the Pan American Health Organization (PAHO) recommends, for example, that each country establish such an agency and fund it at a minimum 1% of the value of a country's domestic drug consumption. It is not clear how this figure was arrived at, but it certainly points to the magnitude of the regulatory problems that confront nations.

CHAPTER THREE

CONCEPTUAL FRAMEWORK FOR A COMPREHENSIVE PHARMACEUTICAL SUPPLY SYSTEM

While the intent of the preceding chapter was to provide some understanding of the dynamic pressures that operate within and around the pharmaceutical sector, the purpose of this chapter is to identify and set parameters for the main components of a comprehensive pharmaceutical supply system. The components selected for discussion have been divided into three groups as follows:

Functional	Evaluative	Motivational
Product Assortment	Access and Demand	Driving Forces
Product Selection	Quality Assurance	Private Property Rights
Procurement	Utilization	
Domestic Production	Cost Parameters	Liability
Distribution and Storage	Integration with the Health Care System	
Inventory and Financial Control		
Pricing		
Promotion and Information		
Research and Development		
Financing and Payment		

It should be recognized that these components are not autonomous entities, but are intrinsically connected through numerous cross-links. A compartmentalization such as done in this conceptual framework is, however, a mandatory requirement for any kind of systems approach to the perplexing difficulties of pharmaceutical sector analysis.

An effort has been made to avoid duplication of information in this and the previous chapter, however, it has not been possible to completely eliminate this duplication without adverse influence on the content and flow of the material included in these manual segments.

As a final introductory comment to this chapter, it should be pointed out that the sequence in which the individual components are being discussed, as well as the sequence among the groups of components, do not reflect a conscious priority ranking. Similarly, the extent of coverage given to each component is not generally intended to signal or imply its relative importance in the overall framework developed here.

The Functional Framework

What is a Product? In comparing the number of products available in one country with that in another country, it is essential to clarify the definitional issues, both in terms of what the word "pharmaceutical" covers--for

example, are medical supplies and devices, cosmetics, medicinal chemicals, pharmaceutical excipients, and indigenous medical remedies covered?--and in terms of what the word "product" means. A brief and most often operationally adequate definition is that a product is a particular pharmaceutical specialty characterized by its dose strength and dose form, sold under a particular designation by a specific manufacturer. A more complete definition reads as follows: "A product is a unique formulation of either a single active ingredient or a combination of active ingredients in a specific dosage form, containing a specified amount of active ingredient(s) and supplied by a specific company under either a unique trade name or a generic name in a unique package get-up or presentation."

The number and kinds of pharmaceutical products available to medical professionals and paraprofessionals as well as to patients/consumers vary dramatically among countries throughout the world, from a high of several hundred thousand in the United States to a low of less than 2,000 in Norway. Many countries lack the administrative capability or legal authority to establish and maintain a precise inventory of its pharmaceutical product assortment. After considerable congressional debate in the United States, the Drug Listing Act of 1972 was finally passed as an amendment to the FD&C Act. Although it took effect in early 1973 and although years of work had already been done by FDA in anticipation of that event, the United States still today does not have a complete inventory nor does it have the necessary machinery to continuously update the inventory.

From a regulatory viewpoint, it is obviously desirable to have as few products--and as few establishments (manufacturers, importers/distributors, retailers, and institutional facilities)--to deal with as possible. Such situations have been created in a few of the developed countries, notably the Scandinavian, through several methods which, however, may not be useful strategies in other countries because of professional and consumer pressures. The methods include:

- Virtual ban on combination products (except where therapeutic synergism among the ingredients can be proven.)
- Strict enforcement of rigorous prescription statutes.
- Ban on pharmaceutical advertising through the mass media, and strict control over professional advertising.
- Maintenance of a pharmacy compounding capability (to ensure physicians of their freedom to prescribe as they deem best, and to provide competition for industrial scale manufacturers).
- Strict systems for registration and licensing of products and establishments (including a steep fee schedule and annual re-registration requirements).
- Strict limitation of consumer access to pharmaceuticals through specially franchised outlets (pharmacies operate under Royal privileges).
- Maintenance of fixed and uniform unit prices to consumers throughout the country.
- Maintenance of uniform retail margins on products combined with a profit-sharing system among all the pharmacies in the country.
- Well developed systems for domestic manufacturing, distribution, and financing of pharmaceuticals.
- Well developed systems for public and professional education.

Because of the wide array of pharmaceutical products and their differing uses, there is a need for some logical grouping of products into smaller units. Several such groupings exist: By chemical structure, by pharmacological action, by manufacturing process, by regulatory status, etc., and it is not surprising that there is little unanimity among nations with regard to the scope and precision of their drug classification systems. Most commonly, a therapy-oriented system is used.

Perhaps the most comprehensive system currently being used is that in South Korea, where the government's production statistics are being grouped into 8 major categories, each of which consist of 4-8 classes, each of which again cover half a dozen subclasses. The system comprises about 250 groupings. However, the Korean Pharmaceutical Industry Association (KPIA) has gone further in an effort to uniformly group products that are still difficult to classify under the government's system; combination products present the greatest problems in such classification systems. KPIA's Directory of Drugs in Korea (1977) shows a system that comprises about 300 groupings.

The international pharmaceutical industry typically operates with a therapeutic classification system of about 100 groupings, which are generally further organized into three major segments: Ethicals, proprietaries, and medical supplies.

The spectrum of pharmaceutical products may be grouped according to many criteria of relative "importance" (therapeutic, economic, sociological, strategic and probably many more), and while matrices may be constructed that can theoretically rank these criteria individually and against each other key judgmental decisions will still have to be made in order to make choices among products. Table 3 is an illustration of this point. The example addresses a key question for health planners: "What is a serious disease?," and simultaneously indicates the difficulties in defining the criteria, assigning ranges for values, and finally measuring the values.

In assessing the value to society of a new pharmaceutical, FDA in the United States considers the drug's therapeutic potential and chemical type and novelty in a matrix with the following dimensions:

Therapeutic Potential:

A. Important Therapeutic Gain
B. Modest Therapeutic Gain
C. Little or No Therapeutic Gain
D. Special Situation
E. Claims for Products under Re-evaluation and for OTC products

Chemical Type and Novelty:

1. New molecular entity (active moiety not yet marketed in the United States).
2. New salt, ester or derivative (active moiety is marketed in the United States).
3. New formulation (compound marketed in the United States, but formulation and dosage form not).
4. New combination (contains two or more components not previously marketed together).
5. Already marketed drug product (product duplicates a drug marketed in the United States by another firm).
6. Already marketed drug product by the same firm (used for new indications for marketed drugs).

The FDA considers a drug to have the potential of offering important therapeutic gain "if it may provide effective therapy or diagnosis (by virtue of greatly increased safety or effectiveness) for a disease not adequately treated or diagnosed by any marketed drug, or provide improved treatment of a disease through improved effectiveness or safety (including decreased abuse potential)." A drug offering modest therapeutic gain is one that would provide "greater patient convenience, elimination of an annoying but not dangerous adverse reaction, potential for large cost reduction, less frequent dosage schedule, and/or useful in specific subpopulations of those with a disease

Table 3

CRITERIA FOR DETERMINING "SERIOUSNESS" OF DISEASES AND CONDITIONS

	Group A	Group B	Group C
Incidence			
Persons afflicted (prevalence)	5% of pop.	1-5% of pop.	1%
Persons diagnosed (morbidity rate per 100,000 pop.)	200	50-100	50
Persons under physician treatment	Most	Some	Few
Persons under other treatment	Most	Some	Few
Severity			
Life endangering (likelihood of death if untreated)	50%	10-50%	10%
Hospital discharges (percent of all hospital discharges)	10%	2-10%	2%
Restriction of personal activity	High	Medium	Low
Reduction of personal income	Great	Moderate	Minor
Personal discomfort	High	Medium	Low
Reduction of life span	50 years	20 years	5 years
Therapy (availability of adequate methods and means)			
Preventability	Difficult	Problematical	Easy
Detectability (accuracy of diagnosis)	Poor	Moderate	Good
Curability without drugs	Poor	Moderate	Good
Curability with drugs	Poor	Moderate	Good
Palliative therapy only	Poor	Moderate	Good
Rehabilitation	Poor	Moderate	Good
Side effects from drug therapy	Severe	Moderate	Minor
Chronicity			
Duration without therapy	life-long	1-20 years	1 year
Duration under therapy	life-long	1-20 years	1 year
Diagnostic monitoring	Continuous	Regular	Infrequent
Recovery propsects	Poor	Moderate	Good
Recurrence, Relapse	Frequent	Moderate	Seldom

(e.g., those allergic to other available drugs)." (The quotes are from the FDA Commissioner's May 5, 1977, Briefing on New Drug Evaluation Project).

Some drugs are deliberately used by medical practitioners as placebos because the key to successful drug therapy is thought to be the patient's belief in the effectiveness of his treatment. If he believes in it, the therapy will work in many instances irrespective of the chemical intervention achieved--or not achieved--through drug therapy.

While a pharmaceutical product assortment for practical reasons cannot officially include inert products, any country's assortment includes products that can be used with a high degree of safety as placebos in therapy; notable among these are many of the water-soluble vitamins. The fundamental issue that underlies the question of placebo usage evolves around the scientific measurement of "efficacy" as determined in national drug registration statutes. Here again each nation must find its own yardsticks to adopt.

Indigenous Medicine: Rapid technological progress during the past decades and associated economic, demographic, and social changes have led to considerable disenchantment with many aspects of contemporary life throughout the world, including modern medical and health care systems. In the developed countries, it has simultaneously become increasingly difficult to find the funds necessary to operate these systems, and policy makers are beginning to emphasize the individual's basic responsibility for his own health and welfare. These developments have led to a re-emphasis on self-medication and a growing demand for many types of indigenous medical practices which until recently, practitioners of "Western" medicine had considered little more than quackery.

In this environment and considering the clamors for better living standards voiced by LDCs and their continuing inability to rapidly finance such improvements, it is not surprising that indigenous medicine has found novel respectability among health care planners and policy makers and that indigenous medicine is now--in stark contrast to earlier times--being advocated for integration into the total health care systems of LDCs.

The First WHO Seminar on the Use of Medicinal Plants in Health Care, held in Tokyo in September 1977, resulted in little more than highlighting the complexities of integrating traditional medical practice with modern health and medical care. Consequently, it may be concluded that any meaningful integration will be long in coming and only be feasible at very considerable costs--the benefits of which are questionable.

International efforts to cooperate in this field are not new. During the past decade, the Federation of Asian Pharmaceutical Associations (FAPA) has sought to establish a common Asian Formulary of compendial standards for the use of the members' native medicinal flora, but real progress has been minimal. One common denominator appears to be the lack of scientifically acceptable quality yardsticks and criteria for selection.

The prevalent serious diseases in LDCs, especially in the rural areas are those (infectious, parasitic, etc.) for which Western medicine is evidently superior to any form of indigenous medical treatment. Thus, WHO's professed support for herbal medicine sounds somewhat half-hearted when one reads the following paragraph in its Press Release WHO/42 of October 27, 1977: "In the least developed countries, where communicable disease control and lack of elementary health care are the major medical concerns, large segments of the population are in urgent need of essential drugs and vaccines. For the optimal use of limited financial resources, the available drugs must be restricted to those proven to be therapeutically effective, to have acceptable safety and to satisfy the health needs of the population."

This discussion should not end without any mention of the reportedly successful integration of "Western" and indigenous medical remedies in the People's Republic of China. Because of its particular system of government and its particular cultural heritage, it is questionable whether the Chinese system is transferable or can be modified to meet the needs of other societies. However, a comprehensive introduction to the Chinese system of providing medical care at the village level, including its diagnostic and therapeutic foundation and the use of botanicals, is available from the illustrated, 942-page American translation of the official Chinese paramedical manual, A Barefoot Doctor's Manual (1977). Nearly one-half of this massive volume is devoted to the identification and description of more than 500 medicinal plants; the description of each plant includes its properties and action as well as the conditions for which it is used most.

Product Selection

The qualitative aspects of determining medical need and therapeutic value underpin the need for local decision-making with regard to a country's, a region's, an insurance program's, a hospital's, or a practicing physician's standard pharmaceutical assortment: A formulary. The qualitative aspects arise as a result of inadequate scientific models to determine "value" precisely, even within the relative narrow boundaries of "health needs." In this context, it should be emphasized that few pharmaceuticals are curative (notable exceptions are those agents that treat infections and parasitic infestation), even fewer are preventive (chiefly vaccines and biologicals), and most are disease retarding, prevent deterioration, or are palliative.

The typical manner in which pharmaceuticals are selected for any program is through a committee of experts. However, this method does not ensure that the range selected is the most appropriate to ensure rational therapy. One problem is that determination and definition of criteria involve considerable judgment, and as Louis Lasagna states in his paper, Consensus Among Experts: The Unholy Grail (1976): "It is not surprising that experts disagree." Lasagna documents the extraordinary extent of disagreement about the efficacy of a number of therapeutic agents (methylphenidate; a fixed-ratio combination of aspirin, ethoheptazine, and meprobamate; injectable vitamin B-12; chloramphenicol; and oral contraceptives) and contends that there are tendencies in our society to regulate the practice of medicine as if "the experts" were unanimous in their recommendations and as if disagreement either did not exist or was trivial in extent and consequence. Finally, he argues that the practice of medicine and its regulation call not for dogma and authoritarian straitjackets but for a fallibilistic and pluralistic approach which is consonant with the real world.

Another problem is that any selection of pharmaceuticals make certain implicit assumptions about their use by professionals and patients. Some of these assumptions are often not warranted as discussed later in this chapter (see "Utilization").

Among the reports and papers that deal with drug selection in LDCs, the following are particularly pertinent. In an interim report prepared for the U.S. Agency for International Development, Procurement and Use of Medicine in Afghanistan (1974), the authors have developed a formulary for basic health services based on assessment of Afghan health problems and judgments by the Ministry of Health in that country, by WHO experts, and by the consultants responsible for eht study. The drug list combines the characteristics of efficacy, simplicity, economy, ease of administration, stability and extended shelf life, and acceptability in the Afghan environment.

In an article appearing in the WHO Chronicle (vol. 31, 1977), "Drugs for Treating Mental Illness and Epilepsy in Developing Countries," the following points are made: "To make a list of drugs that would command general agreement presents difficulties for various reasons, e.g., variations in diagnostic criteria in different countries and cultures, variations in the clinical presentation of mental disorders, insufficient knowledge about the mechanisms of these disorders and of drug action, and variations in the genetics, general health, and nutrition of populations."

In a recently completed report for the United Nations Conference on Trade and Development (UNCTAD), Case Studies in Transfer of Technology: Pharmaceutical Policies in Sri Lanka, (1977), the author, Dr. Seneka Bibile, who was instrumental in the reorganization of Sri Lanka's pharmaceutical sector during the early 1970s, provides several interesting insights into that country's system for selecting drugs.

Most of the criteria for drug selection reviewed here can be fitted with the regulatory concepts listed in Chapter III of this Manual (see "Focus" in the section on "Government Intervention").

Essential Drugs: WHO's initial effort to determine which drugs are essential for basic health needs was a conference among a few experts held in Geneva in October 1976. The results were published by WHO in an interesting report, Consultation on the Selection of Essential Drugs, which included a listing of some 150 drugs selected based on the following criteria:

"In the selection of essential drugs, top priority must be given to drugs with proven efficacy and accepted safety in relation to common and important symptoms and diseases.

The selection and use of a drug should be adjusted to the level of health care, i.e., facilities and the type of skill of the actual health care workers.

Moreover, the criteria for the selection of essential drugs should primarily be based upon accepted scientific documentation within the pharmaceutical, pharmacological, clinical and other relevant fields. Complementary criteria include local therapy tradition, cost factors, product accessibility and availability, storage facilities, as well as patients' acceptance of the drug.

If scientifically acceptable data are lacking or are inappropriate, this should be clearly stated if a less documented drug is to be adopted in health practice.

Epidemiological, genetic, demographic and environmental factors differ among countries and regions and lead to discrepancies in the decision on which drugs are considered essential. Correspondingly, changes and differences in local hygienic conditions and patterns of prevalent diseases may also influence such a drug selection.

The concept that a new drug is necessarily a better alternative than those already existing should be questioned, not least because an unnecessarily large number of drugs tends to add to the general confusion in the utilization of drugs.

Combination drugs should not be chosen or used unless a superior efficacy--as compared to that of each single compound--is clearly proven.

Drug demand (as claimed by society, the medical professions and/or the drug industry) is not necessarily congruent with drug need. The handling of this problem must be part of a more general decision at local and country level, in the field of health and drug policies."

Procurement

As some other components of the pharmaceutical supply system, the procurement component may be grouped into three models: A centralized system, a decentralized system, and a mixed system. Because of the decision's multisectorial implications and ripple effects within the drug sector, national policy makers need to carefully consider the goals, policies, and characteristics of their own countries before deciding on a particular model.

In this context, the budget allocation process is one crucial variable since no procurement system can operate effectively unless it has adequate time and funds to formulate and execute a particular procurement strategy.

In recent years, the centralized system--which places sole responsibility for purchasing in a state enterprise--has been strongly advocated in various reports and resolutions, including several by UNCTAD, WHO, and the Organization of Nonaligned Countries.

Among the developed countries, only Norway has operated a centralized procurement system for more than 20 years. The objectives of the Norwegian model appear to be less concerned with cost-savings aspects than with quality, assortment, and orderly distribution of pharmaceuticals. Perhaps the greatest advantage associated with this system is the sophisticated data base it has given planners and policy makers to work with. However, there is not unanimous satisfaction with the Norwegian model.

Several LDCs have also had considerable experience with the centralized procurement model, however, the record of success and failure is not entirely clear. One reason is that little descriptive information and no objective analyses are available from the literature. Judging from mostly anecdotal information, the experience of countries such as Iraq, Syria, Algeria, Tunesia, Burma, and Tanzania have been less than satisfactory.

For these reasons, it is fortunate that the earlier mentioned UNCTAD report on Sri Lanka provides a picture of Sri Lanka's transition from a mixed to a centralized system. Following an inquiry into the pharmaceutical sector by a government-appointed team in 1970-71, a State Pharmaceuticals Corporation (SPC) was established to eventually monopolize pharmaceuticals import for both the public and private sectors.

The guiding principles were:

- Reduction of the number of pharmaceuticals in the private sector from 2,100 to 600.
- Introduction of generic names instead of brand names.
- Bulk purchasing.
- Careful quality control.
- Expansion of domestic drug production.
- Provision of adequate drug information.
- Careful inventory control combined with a system for demand forecasting.
- Introduction of a uniform wholesale and retail pricing system according to a fixed formula.

Although the report states that: "The strong components of pharmaceutical policies implemented in Sri Lanka are product selection, procurement, distribution, and product information. The developing components are production and monitoring of product utilization."

While the UNCTAD report by Bibile does emphasize that the national buying agency achieved foreign exchange savings it makes no claim that the country has achieved any cost savings or that the quality and scope of pharmaceutical services improved.

Decentralized procurement systems rely to a large extent on the free enterprise market concepts or, more accurately, on an active market mechanism, featuring a competitive supply and demand situation. In LDCs, such a procurement policy is understood to be pursued in, among others, South Korea, the Philippines, Singapore, and Malaysia within the broad boundaries of product registration, allocation of foreign exchange, and perhaps also price controls. This model achieves the best balance between supply and demand within normal economic parameters and, thus, is the one generally advocated by the business community. The successful operation of such a decentralized system demands close cooperation between the private and public sector, and government officials need to be convinced that they obtain sufficient data from the private sector to shape overall policies to prevent shortages, to achieve optimal inventory turn-over, etc.

The mixed model which combines elements of the centralized and decentralized models is the most common one in the LDCs. Typically, the public and private sectors operate their purchasing systems with little coordination between them, a situation that leads to the existence of two separate pharmaceutical supply channels. Often these compete for foreign exchange and for customers with the private sector supplying those who can afford to pay for their needed products and services; the public sector is essentially left to provide for those who cannot pay. Since the latter group of customers is numerically by far the largest, the pressures for low unit acquisition costs and "cheap" pharmaceuticals is felt much more strongly in the public sector procurement agencies. The result is often that low quality (inferior shelf-life characteristics, brand discontinuity, inappropriate bulk packaging, lack of suitable patient packs, etc.) pharmaceuticals is associated with public sector drug therapy.

In the mixed model, the public sector agencies commonly effect purchases through international tenders and because the tender conditions often are not acceptable to the large international pharmaceutical companies, tenders are often awarded to smaller foreign firms which supply their own brand name copies of products that already are well established in the country's private sector system. This, then, is one of the factors that leads to product duplication and proliferation.

Any country needs to develop its own procurement policy for pharmaceuticals based on critical evaluation of its current practices and with due regard to realistic alternatives. Changes from one model to another and especially the adoption of a centralized procurement system should probably not be attempted abruptly and without adequate consultation with recognized spokesmen for the major societal pressure forces in the country. Careful market research studies should precede direct negotiations with those suppliers who currently hold important market segments, so that the possibilities for long-term future collaboration that yields acceptable benefits to both parties can be explored. It is thought to be particularly important that public sector negotiators can speak with authority for the entire public sector--this may require an intra-government commission with delegates from the Ministries of Health, Defense, Interior, etc.--and negotiate directly with domestic as well as foreign suppliers, preferably manufacturers, in order to establish close contacts with the original source.

LDCs that cannot devote the administrative resources required for a "hands-on" pharmaceutical procurement policy might consider cooperative purchase arrangements such as those now being attempted in the Caribbean or, in order to retain more sovereignty, "chartering" a private firm to handle all or a substantial portion of the country's drug procurement. Models for the latter

approach include the Warner-Lambert organization in Zaire and the London firm, Crown Agents.

Finally, in devising a procurement strategy, health planners should recognize that attempts to circumvent the economic dynamics of the marketplace will lead to increasing needs for coercion and regimentation, the direct and indirect costs of which may be unacceptably high.

Domestic Production

Much information is available from the literature on the topic of pharmaceuticals production in LDCs, but for the major part, the writings are in the cause of advocating industrial development rather than improving the supply of high quality, low cost pharmaceuticals to the needy population segments. One of the more objective reports in the field is one prepared by the United Nations Industrial Development Organization (UNIDO), Establishment of Pharmaceutical Industries in Developing Countries (1970) which contains numerous specific recommendations for action. Among others, the report suggests that the following matters be investigated and assessed before a suitable plan can be prepared for the introduction of a pharmaceutical industry sector in a developing country:

- "Data on the general economic and hygienic standards of the country;
- Demographic data, such as the population of the country, average life expectancy, population structure and increases, and general attitudes of the population concerning medical treatment and pharmaceuticals;
- Local patterns of medical treatment and its costs;
- The existence and prevalence of diseases and common ailments, especially those of an infectious and epidemic nature;
- Medical care available, the number of practicing physicians, nurses, hospital beds, pharmacies, pharmacists, technicians in the medical area and scientific personnel in sciences related to medicine;
- The size and the nature of the existing local pharmaceutical market, the traditional supply and distribution system, price levels and pricing structures;
- Laws regarding the importation and distribution of pharmaceuticals, company policies and industrial laws, taxation, custom duties and protection of industrial property;
- Local availability of trained and/or trainable manpower for assignments in the pharmaceutical industry;
- Availability of packaging materials for pharmaceutical preparations and the development potential of this area;
- The present and projected demand for pharmaceuticals, classified in therapeutic categories;
- Potential export possibilities and regional and interregional cooperative plans;
- Therapeutic and prophylactic requirements of food-animal and work-animal populations;
- General attitudes towards foreign assistance or investments, and incentives and protection policies, if any;
- Industrial feasibility of the manufacture of selected pharmaceuticals. (Such an assessment should be undertaken jointly by WHO, FAO and UNIDO, and should be carried out not only by pharmaceutical, veterinary, medical, financial and economic advisers of the organizations, but also by specialists resident in the respective developing countries or regions.)
- Data on human therapeutic requirements, treatment patterns, and treatment costs. These can be obtained from:

(a) Physicians and veterinarians familiar with the local situation;
(b) Statistical data on drug imports;
(c) Indicated demand of drug consumption obtained, for example, from local sickness boards or from records of local hospitals and military pharmacies;
(d) Representative samples of medical prescriptions by hospital physicians and general practitioners."

The major omission in this listing is an assessment of current and potential future alternative process, manufacturing and treatment technologies.

The report also recommends that the establishment of a pharmaceutical industry should not be undertaken merely for reasons of national prestige or to conserve foreign exchange, and that LDCs "may be well advised to encourage experienced foreign pharmaceutical organizations in establishing facilities to initiate sectors of a pharmaceutical industry and should provide adequate incentives and protection."

Without protective import tariffs, empirical evidence suggests that by far the majority of LDCs would be able to gain access to competitively priced pharmaceuticals of their choice from foreign sources. Otherwise, why would small developed countries with relatively well entrenched domestic industries such as Denmark and Sweden--which are among the very few countries that levy no duties on pharmaceuticals--obtain half their supplies of specialties from abroad?

South Korea is undoubtedly the LDC that has pursued the most successful national industrial development policy in the pharmaceutical sector among all developing countries, as further described in The Yakup Shinmoon's bi-annual publication Pharmacy in Korea (latest issue 1977). The critical feature of the Korean model has been close cooperation between domestic entrepreneurs and the government, characterized by government intervention to protect the national industry through tariff barriers on specialties and medicinal chemicals, foreign investment restrictions, and some disregard for industrial property rights (patents, trademarks, copyrights) as well as by nonintervention by the government in the workings of the domestic market mechanism. The latter is the more remarkable since pharmaceuticals still account for more than 50% of South Korea's national expenditures (current account) on health care.

Many LDCs have opted for a mixed private/public sector production strategy; for example, Brazil, India, Mexico, Indonesia, Nigeria, and Thailand belong in this group. In most cases, the public sector factories are not competitive with those in the private sector and only stay in business because of special government protection (production as well as supply monopolies), a situation that leads to often detrimental competition between the two sectors. Aspects of this situation is explored in another recent UNCTAD publication, Case Studies in the Transfer of Technology: The Pharmaceutical Industry in India (1977).

Total government ownership of pharmaceutical production facilities does not seem to improve the availability or quality or lower the cost of pharmaceuticals to the most needy population segments--judging from the past and present experiences of countries such as Indonesia and Burma. Nevertheless, this approach is now again being attempted in, for example, Algeria and Tunisia.

Some LDCs apparently recognize the complexities of pharmaceutical production and have decided to seek joint venture arrangements between the public and private sectors. The latter is frequently represented by large multinational pharmaceutical corporations whose contribution is often limited to know-how, including management. Brazil, Egypt, and Nigeria provide examples of this nature.

Normally, it should be taken for granted that production of multi-source medicinal chemicals in LDCs can only be effected at a premium in cost over their "international selling price." The question is, thus, not whether a given substance can be produced competitively in LDCs, but what premium in price the country's local formulators can pay; this, in turn, is usually decided by the government's product registration, import duty, pricing and distribution policies on specialties.

The quality aspects of domestic production have been discussed earlier, see Chapter Three, "Government Intervention," section on "Regulatory Tools and Issues" under the topic-heading "GMP," and are further dealt with later in this chapter (see "Quality Assurance").

Distribution

The distribution function is another key component in any pharmaceutical supply system, and the one that perhaps most clearly illustrates the problems confronting planners and policy makers who seek to overcome economic barriers in an effort to further social justice and equity in the pharmaceutical field. Western drug therapy and universal economic laws guiding the demand and supply of goods and services clash particularly in rural areas of LDCs because of insufficient availability of professional knowledge, inadequate lay educational levels, an insufficient economic base to permit the existence of an efficient transportation and warehousing system, and lack of consumer purchasing power needed for a segmented and competitive network of retail stores.

An article in the WHO Chronicle for October 1977 (Vol. 31), A Vital Link--Ensuring Supplies of Medical Equipment and Drugs Where Really Needed suggests that a medical commodities distribution system is a new concept in many countries, and that setting it up may be a medium-term or even long-term undertaking.

It defines the functions and structure of such a system as follows: "A medical commodities distribution system can be defined as a method of establishing a regular channel of distribution and communications between the central level, through intermediate levels if necessary, to the level of the outlying community. Its functions, in support of primary health care, include the following:

(1) To obtain, store and distribute at regular intervals the medical commodities necessary to support the public health programme in each rural community;
(2) To collect data at regular intervals from the communities on public health programme activity and the utilization of medical commodities;
(3) To transport the personnel and information needed to reinforce supervision and training of rural staff;
(4) To provide regular preventive maintenance for medical equipment used at the intermediate and peripheral levels;
(5) To support field staff members by serving as a regular two-way channel of communication;
(6) To ensure that the system itself has the transport capacity it needs and to prevent breakdowns by providing for regular maintenance of the vehicles used.

Setting up a system of this kind will involve certain common elements:

- A central-level delivery unit, responsible for policy and planning and for delivering medical commodities to health units in the rural communities (or to regional--intermediate--depots where they exist).

- A procurement unit, responsible for procuring the medical commodities needed and maintaining a stock sufficient to meet requests from health units.
- Regional depots (where required by the country's geography), responsible for receiving commodities dispatched from the central delivery unit and for forwarding them to community level, and also for maintaining 6-12 month buffer stocks of priority commodities so that they are always available when requested by peripheral units.
- A medical equipment maintenance unit, responsible for the preventive maintenance and repair of medical equipment."

Although not explicitly stated, the article appears to only be concerned with supplies in the public sector system which often handles only a small fraction of the total supplies that must be distributed.

As the situation is now in most countries, developed as well as developing, pharmaceuticals have the same legal status in business as any other commodity, and they are subject to the same laws and regulations that govern other consumer products--with the exception of prescription drugs. Prescription drugs may normally only be sold to pharmacists, pharmacies, drugstores, physicians, hospitals, clinics, nursing homes and similar institutions specially qualified to use these types of pharmaceuticals on patients or to prescribe their use. The reason is that public policy makers perceive consumers/patients have inadequate knowledge to use prescription pharmaceuticals safely and effectively.

Thus, the right to prescribe pharmaceuticals has become one of the central features of a Western pharmaceutical supply system. Another key factor in this system is the prescriber's freedom to choose the product he wants to use in his therapy. Since prescribers are physicians who are licensed according to professional standards over which governments often have little actual influence, and since the physician, not the nebulous "government," is responsible for the life and well-being of a patient under his care, it is not surprising that the physician has become the crucially important point in the distribution system.

In the LDCs, the physician's role is shared with that of the pharmacist, as further discussed in Chapter Three (see "Pharmaceutical Supply Systems," the segment on "Patient Access Systems"). One reason is that regulations on prescribing prerogatives are broader and less vigorously enforced than in the developed countries. Another reason is that--with the normal exceptions of biologicals, narcotics, and psychotropics--prescription drugs are frequently sold as freely as OTC drugs; until a few years ago, antibiotics were, for example, advertised on TV in South Korea.

In this situation, it is normal that the physician in private practice derives the larger portion of his income from the sale of pharmaceuticals, that the pharmacist often is the primary health care worker and, as such, also engages in diagnosis and therapy, and that consumers exercise widespread self-diagnosis and self-care. The shortage of professional manpower, especially in the rural areas of LDCs, has led many governments to license--or tacitly accept--various other outlets as retail distribution points beyond those mentioned above. Usually, however, retailers such as druggists, drug sellers, and herbalists are allowed only to handle increasingly harmless drugs according to their level of education.

All this has the effect of emphasizing the commerical rather than the professional and informational aspects of the pharmaceutical supply system. Efforts by LDC governments to intervene have usually failed for lack of understanding of the forces of the marketplace and/or for lack of capabilities to enforce compliance with interventionist regulatory measures.

Wholesaler-based monopolies might be an effective method by which LDCs can best approach the problem of expanding the urban pharmaceutical supply system into rural areas. These monopolies might cover all sectors and one monopoly might be responsible for a balanced mix of poor and rich customers (institutions, clinics, retail shops, etc.). By having several wholesaler monopolies each covering only a part of the country, it should be possible to ensure the necessary amount of healthy competition among them and responsiveness to professional and consumer needs. Some major advantages of such a system should be the establishment of an excellent data base; relatively easy intervention in many facets of the pharmaceutical supply system through simple administrative measures and thus ensure regulatory flexibility; and curtailment of the present situation in many LDCs where all kinds of pharmaceuticals float around more or less freely in the marketplace. It might be preferable to "charter" companies in the private sector to perform these wholesaling functions on a multi-year basis since this would also give the government the option of inviting foreign companies that possess the necessary know-how and management staff to bid on such monopolies.

The monopoly approach is already well-known. Earlier in this section on "The Functional Framework" (see "Procurement") reference has been made to the Norwegian state enterprise, which in addition to its import monopoly also has a monopoly on pharmaceutical wholesaling. The similar situation exists in several LDCs, notably in the Middle East.

In many LDCs, this problem of volume and mix is one of the causes why retailers try to deal directly with suppliers rather than through wholesalers. In order to obtain their supplies at competitive prices, they have to purchase more than their retail requirements; their excess supplies are sold wholesale. These factors have caused the virtual disappearance of true wholesale establishments in many LDCs. Creating wholesale monopolies will therefore introduce a third link in the distribution chain, a link that, however, already exists albeit often in the guise of a retail pharmacy.

Since it is not uncommon that pharmaceuticals are traded several times among pharmacies before finally being sold to a consumer--or an institution or a physician--the wholesale drug monopoly system should reduce waste (broken, soiled, crushed packages; expired goods) and perhaps even lower the total distribution costs. Likewise, commercial trading practices--ranging from discount and bonus goods arrangements to return goods policies--might become subject to more unified methods than those that currently characterize the market for pharmaceuticals in LDCs. This should, in turn, lead to improvements in the overall quality aspects of the pharmaceutical supply system.

Transportation in LDCs and particularly in the rural areas provide obstacles that are difficult to understand for people who have not had personal experiences with traveling and sending goods into the "hinterland." Wholesale drug monopolies might be better placed than current middlemen to work with a wide variety of public and private sector transportation systems--that use roads, railroads, rivers, lakes, and the air--if there is support by the government for special status in commerce and in the health care system of these monopolies.

The lack of adequate storage facilities for many types of drugs that require special care and handling is another major problem that an efficient distribution system must overcome. Local initiative and ingenuity are the only permanent measures that will alleviate this situation, although outside agencies such as WHO may develop certain models for ways in which specific problems can be dealt with. An example is provided in the WHO Chronicle (Vol. 31, 1977), "Improving the Cold Chain for Vaccines."

The article summarizes the well-known problems that face LDCs, particularly those with tropical climates, in establishing and maintaining a cold chain, and describes a pilot project being carried out in Ghana that may help solve many of these problems.

The approach discussed in the article relies heavily on Ghanaian resourcefulness, and experiences made could be useful in solving the difficult problems of the cold chain elsewhere in the LDCs.

Inventory and Financial Control

Within the functional framework of a pharmaceutical supply system the operational aspects that deal with inventory and financial control are among the most important. Accounts of pilferage, of losses from inappropriate storage, of losses from poor warehousing procedures, and similar signs of lax management of and accountability for pharmaceutical supplies by the responsible public sector entities are common throughout the developing world. The deficiencies and irregularities are thought to be so widespread that lack of know-how in establishing and operating a reasonably efficient and sound warehousing system do not alone explain the existence of these problems.

This point is the more valid since there is no scarcity of management consultants who offer appropriate expertise to deal with the symptoms of these problems. In this connection, it may be noted that the Public Health Service of the United States has its own well established procedures, some of which are readily available from its Medical Supply Depot Operations Manual.

However, the introduction of an appropriate management system to deal with the existing symptomatic problems will serve little purpose unless the real causes of the irregularities and deficiencies are identified and adequate remedial action is taken. Again, the particular characteristics of each country's situation determine the most useful approach to take and the following points, therefore, merely serve to emphasize the importance of some key variables.

The foundation for all good recordkeeping in business is detailed merchandise vouchers: Invoices, credit notes, debit notes, packing lists, etc. Warehouse managers should not accept or release goods without such vouchers.

Each level in a centralized distribution chain--central warehouse, regional depots, hospitals, clinics, dressing stations--should ideally keep its records based on the same procedures for that particular level. The calculation work should be done centrally, and the applicable unit rates for each level should be set by fiat by the central warehouse administration.

Obviously, the number of products in the inventory determines the magnitude of the recordkeeping work and, thus, the vulnerability to errors, etc. of the whole system. With "product" defined in its strictest sense, it would be normal in countries with small assortments to have an actual inventory of 10,000 items, but examples of such "small assortment" countries with both 5,000 and 15,000 stock numbers can probably be found quite readily.

To curtail the number of items, it is tempting to designate similar products by generic name, however, this is not advisable because each particular lot of pharmaceuticals should be traceable for the purposes of possible recalls, possible liability placement, possible special warnings, etc. Switching to a generic nomenclature in recordkeeping would, further, defeat one cardinal reason for the entire control system, namely, traceability.

This traceability is needed not only for financial control, but also for the physical inventory control. Without it, expensive and high quality products may readily be substituted for cheap, undergrade products. Such stock switching is, of course, much more serious from a public health viewpoint than merely for financial considerations.

Another attempt at reducing the inventory size also widely practiced in business, namely arbitrary deletion of products with an annual volume below a certain level, does not work in the pharmaceutical field either because many products must be carried in stock. It is customary to monitor with particular care the inventory levels of those products--typically 20%--that represent 80% of the transactions.

Physical control over inventory levels is best maintained in LDCs through a simple index card system that relies on hand entries if manpower and capital budgets do not permit computer systems. In addition to recording the normal data concerning stock entry, exit, current level, batch number, special storage requirements (e.g., temperature, light, physical turning of bottles with liquid to avoid sedimentation; narcotic and psychotropic substances safeguards), shelf life, etc., the card should also specify the desirable minimum/maximum inventory levels and lead times for stock replenishment. Thus, the card also becomes an instrument by which purchase or manufacturing requisitions can be timely issued.

Inventory checks should be carried out regularly. Where pilferage, spoilage, outdating, return goods and other avoidable occurrences seem to cause chronic problems in the physical product portion of the pharmaceutical supply system, such checks should be carried out at least quarterly without prior notification to the daily warehouse personnel. Cartons and crates should be physically moved, and selectively opened and inspected for integrity of contents; compromised merchandise should be quarantined until proper disposition can be made by qualified personnel.

Financial and physical inventory responsibilities should be vested in separate departments to ensure that a minimum system of checks and balances exists. Their objectives from a business viewpoint are not always the same, and in such situations, it is probably advisable to give priority to the physical rather than the financial aspects of controlling and optimizing the use of the inventory. The limited keeping quality and particular storage requirements of many pharmaceuticals mandate that the FIFO (first in, first out) method be used in pharmaceutical warehousing operations.

The absence in many LDCs of a well planned and well run financial and physical inventory system in undoubtedly one of the chief, practical obstacles to an efficient pharmaceutical supply system. Since the proper management of inventories depend more on the quality, integrity, and commitment of the individuals than on the system they operate, the questions of motivation of the responsible staff are the crucial problems. While this is true of any system, the fact that the physical product is easily within reach of warehouse personnel in the inventory systems makes the latter a particularly vulnerable component of the entire pharmaceutical supply system.

The key element in maintaining the internal integrity of an inventory and warehousing system is close supervision. Supervision should permeate all strata of warehouse activity, including posters, drivers, inventory clerks, billing clerks and cashiers. Top management should and must monitor the supervisor system on a conscientious and continuing basis.

Pricing

The concept that suppliers of pharmaceuticals have an unfair advantage over consumers, especially where prescription drugs are concerned, is firmly rooted throughout the world. Therefore, it is not surprising that the pricing mechanisms in the pharmaceutical supply system have been the topic of more investigations and debate than any other consumer product, and that the governments in most countries have devised their own methods of intervention. The focus has primarily been on manufacturer's prices.

Since the drug pricing issue continues to elude rational and comprehensive analysis and therefore is an emotional and politically sensitive problem, little use will be served by delving into the various postulations or hypotheses in this manual. Rather, some overview and background information will be provided.

Because of the many factors--including the pressures on national economies of rapidly escalating health care costs and the claim by pharmaceutical manufacturers that restrictive drug pricing policies are impeding the financing of pharmaceutical research--governments throughout the developed world have intensified their efforts to develop new pricing systems. The trend in these new models appear to be that governments are beginning to depart from the earlier policy of applying price regulations uniformly in favor of a more company-specific approach. This approach is leading to the segmentation of the drug industry into two categories as far as pricing is concerned: One comprises the research-intensive firms, and another comprises the merely production and distribution oriented firms.

In examining pharmaceutical pricing patterns at the manufacturer's level, it is always necessary to consider the specific product type concerned. Broadly, products can be divided into three groups: Ethical originals, ethical generics, and proprietaries; these may again be divided into three categories: Own developments, licensed products, and copies. Ethical originals developed internally are normally priced at the "higher" end of the spectrum while proprietary copies are priced at the "lower" end.

A few comments are now appropriate with regard to distribution costs and mark-ups, a task that is hampered by a considerable lack of discussion of these topics in the literature.

In the developed countries total distribution margins range from 40% to 55% while in the LDCs they tend to be in the range of 25% to 40%. All margins are calculated on sales rather than purchase price. This difference in distributive margins may offer one explanation as to why the physical distribution system in LDCs is somewhat deficient compared with that in the developed world.

The aim of a pharmaceutical pricing policy must be to develop a flexible mechanism that assures consumers of being charged only a "reasonable" price for any given drug, but especially for those that may be classified as "important." It must be a further aim that this price is uniform throughout the country, and that subsidies--in one form or another--are available from the public sector to those members of society who cannot afford to pay this "reasonable" price out of their own pocket.

Product Information and Promotion

Some of the pertinent aspects of this component have already been discussed in Chapter Three under "Pharmaceutical Supply Systems" (see "Communications Systems"), and since this general topic is well covered in the professional and lay literature, this section will be confined to a brief overview of some issues that need to be addressed by decision-makers in LDCs in order to shape public policy.

The magnitude of the problem must be assessed. The size of the population, its level of education, the number of health professionals, the size of the product assortment, and the number of private sector competitors tend to combine to set the dimensions of the problem.

Some regulatory controls over pharmaceutical promotion and information have been considered absolutely necessary in virtually all countries in order to protect the perceived gullible and ignorant consumers from callous exploitation by the suppliers of pharmaceuticals. This intervention has led to more

and more government controls, the administrative cost and effectiveness of which cannot be assessed with much validity.

If LDC governments were to invest some of their scarce resources in exploring the likely implications of specific interventions in current drug informational and promotional practices, many of them would probably conclude that the best way to proceed would be to do little or nothing to change the current situation.

Particular care needs to be given to intervention in the prescription drug segment because of the prerogatives of medical professionals to diagnose sickness, prescribe therapy, and care for the sick. This is probably the reason why several countries with centralized procurement and distribution systems such as Burma, Syria, and Iraq permit foreign suppliers to maintain so-called "scientific offices," which provide "free" informational/promotional services to the medical/pharmaceutical community.

One of the fundamental differences between the LDCs and the developed countries with regard to their pharmaceutical supply systems is the LDCs' much greater reliance on self-care. While the typical reason given for this situation is given as their comparative lack of adequate health care resources--money, manpower, materials, management, and methods--the common implication that this degree of self-care is unfortunate is debatable.

In the LDCs, there are undoubtedly promotional abuses such as excessive trade deals, samples, gifts, and bribes in one form or another, and similarly, there are informational abuses with regard to product claims--abuses that in many countries are much more prevalent among the domestic, national industry than among the large pharmaceutical multinational corporations--and these need to be curtailed but probably not entirely suppressed. Perhaps the most effective method by which regulators can work to achieve such curtailment is through nonstatutory guidelines or, where industry organizations exist, by having codes of good marketing practices already in existence in various developed countries suitably adopted to local LDC conditions.

Overcoming the illiteracy barrier or language barriers can be accomplished, but with difficulty and not without added risks of misunderstandings leading to inappropriate use. However, on the theory that some printed information particularly about prescription drugs is better than only oral information (typically provided by sources with minimal professional competence) leaflets with pictorial instructions about dosage have been used in some countries, including Afghanistan. There may be some question that enough efforts have been devoted to this approach.

Research and Development

The research and development (R&D) component of the pharmaceutical industry has not received much attention in LDCs in the past, whereas in the developed countries it has emerged as another key problem. This applies particularly to product-oriented research because this activity is financed to a unique extent--probably more than 90%--by private sector capital; by contrast, most other high-technology research is funded by the public sector with private capital in some cases contributing as little as 10% (aircraft industry).

Empirical evidence suggests that in drug research no mechanism has yet been found whereby the public sector can productively take a significant part in more than the basic research process. Efforts to "rationalize" drug research through a central mechanism which should lead to elimination of perceived duplication and waste are not likely to succeed in smaller LDCs.

This situation and the fact that serious pharmaceutical research is an expensive, multidisciplinary, and extremely risky undertaking directly rank

the R&D component to virtually all other components of the pharmaceutical supply system, to the overall health care system, and to general national development strategies and policies. These and related topics are explored in a paper presented by the author of this manual to the Academy of Pharmaceutical Sciences, "Pharmaceutical Research: An International Quest for Technology" (reprinted in the November 1977 issue of Medical Marketing & Media).

While discovery-oriented, basic research to develop new "Western" pharmaceuticals is not likely to emerge as an important factor anywhere in the LDCs for many years to come, clinical research is beginning to appear throughout the developing world. This is an important technological development since this type of research is needed in order to obtain the safest and most effective dose-regimen in specific populations for particular prescription drugs. However, simultaneously it continues the "Western" pattern of what may be termed "scientific medicine." The problem with this is that indigenous medicine and remedies, which still constitute the main health care system in most LDCs--and which public health planners now advocate should be strengthened and "integrated" with "Western" medicine--cannot (yet?) stand up to similar scientific scrutiny and pass sophisticated testing.

Much interest is now evident in the potentials of using the plant resources of LDCs as an alternative source of raw materials for a national pharmaceutical industry.

One key problem to overcome would be, for example, to determine exactly which naturally occurring plants, trees, roots, etc. provide the best resources and how to cultivate such products under controlled conditions. Efforts to do exactly this with the barbasco root--which continues to be one of the main sources of steroids--have failed, although determined attempts have been made in many countries; thus, the naturally occurring product in Mexico remains the world's largest resource. Similar examples for other botanicals indicate this problem of sourcing to be a key problem which can only be overcome through carefully targeted R&D.

Special research institutes devoted to the study of indigenous medical practices and remedies are now common in the LDCs, especially those in Asia where notably China, Japan, Taiwan, Indonesia, India, Pakistan, and Iran have active programs.

The need for pharmaceutical R&D is obvious when one considers the universal requirements for refinements in current drug therapies. New pharmaceuticals are urgently needed that feature fewer side effects, longer lasting efficacy, easier administration, greater adaptability to individualized treatment, lower cost, longer shelf life, and--where antibiotics are concerned--lesser propensity to generate microbial resistance. These types of "new" products are generally refinements of existing ones.

The need for pharmaceutical R&D is also obvious when one considers the universal requirements for entirely new drug therapies. As mentioned elsewhere in this manual, it seems to be increasingly accepted that solutions to problems affecting the pharmaceutical supply system must be found through collaboration between public and private sector interests. This approach is now also evident in the system's R&D component.

R&D is one of the components in the pharmaceutical supply system which is particularly subject to the pressures of international or supranational development. Therefore, it is hardly realistic to shape a pharmaceutical policy even in the most impoverished LDC without some consideration of the likelihood for process and product innovations somewhere in the world that might have important implications for improved health care in the country. Several organizations offer a variety of services to enable researchers and others to keep abreast of research developments, but all require considerable expertise on the user's part and some of them are quite expensive.

There is a substantial body of literature devoted to the prediction of areas where particular research breakthroughs are most likely to occur, however, since research is inherently an uncertain undertaking, predictions in the field of drug discovery should not be taken as guarantees.

The Evaluative Framework

Several barriers exist to limit the demand for pharmaceuticals. As put in Stanford Research Institute's Pharmaceutical Industry Dynamics and Outlook to 1985 (1976): "Fundamental factors causing the demand for the industry's output include a range of specific demographic and cultural characteristics, aspects of medical practice, and disease patterns. The size of the demand is essentially still limited only by product and service availability, and by the ability of consumers and/or social or other services, to pay for pharmaceuticals and associated services."

In a report by the Director-General of WHO to the 28th World Health Assembly, Prophylactic and Therapeutic Substances (1975) the problems of demand are discussed in the following terms: "The effective demand (i.e., need plus ability to pay) for any pharmaceutical product is influenced by many factors. One can estimate the population at risk, those who have a need for the product and those who have a potential need, based on present and future estimates of the prevalence of the disease the product is intended to treat. This would give an estimate of the maximum potential market for the product and must be modified to reflect the influence of other factors such as the inaccessibility to health services of certain segments of the population at risk, the inability to pay for the product in the private sector, the health awareness and the cultural attitudes of the population which may affect demand, the effectiveness of product distribution and promotional efforts by the manufacturer among the health professions and the public in fostering demand. Thus, the effective demand for pharmaceutical products is considerably affected by the availability, utilization and distribution of health service, by population and income distribution, by health education, and by activities of drug manufacturers and by any governmental action on the above.

In the least developed countries, little relationship may be found between the major health problems of the country and the size and structure of the country's drug market. The main reason is that, whereas the major health problems--in terms of communicable disease control and primary health care--encompass the entire population, the pharmaceutical market relates mainly to the relatively small, more fortunate, segment of the population, usually living in urban areas, which has access to health services in both the public and private sectors. The health problems of these areas are usually quite different from those of the country as a whole. Even in countries where the incidence of parasitic diseases is highest, the effective demand for products to treat them is realtively insignificant. The solution to this problem obviously lies in the improvement and extension of health services in rural areas. In most countries, governmental health planning is almost exclusively concerned with the desired increase in hospital beds and community health facilities and with the training of health manpower, whereas little attention is paid to the assessment of the country's needs for pharmaceutical products in both the public and private sectors."

As already discussed earlier--see for example Matrix 1 and the many variables listed under "[illegible]" in Chapter Three's section on "Government Intervention"--it is only possible to establish criteria for a country's needs for pharmaceutical products after a series of assumptions have been made. However, the validity of these assumptions is subject to great change even

over short periods of time and, therefore, one may conclude that there are no acceptable and universally applicable yardsticks or methods by which pharmaceutical needs can be measured.

Under these circumstances, it makes sense to hypothesize that demand equals needs except to the extent that this equation is undermined by imperfect consumer access. These imperfections essentially deal with economic barriers or constraints that can be measured in time; and with socio-cultural education, and communicative barriers that probably cannot be measured. In evaluating the efficiency or adequacy or equity of a country's pharmaceutical supply system one must, thus, focus on areas of government intervention that improve or impede or set other parameters for access to pharmaceutical products and services. These areas have been discussed earlier in this manual, and other manuals in this same series of "Guidelines for Health Sector Analysis" provide additional information.

One of the difficult problems faced by LDCs and developed countries alike is that the concept of conscious quality differentiation is, in principle, totally unacceptable in the case of pharmaceutical products. Only the highest quality is acceptable. This principle is being tested particularly in the LDCs since the costs of quality and quality control must be incorporated in the product's price. The problems of different quality yardsticks for pharmaceuticals produced and used in the developed countries and those available in the LDCs is likely to grow in future years judging from the significant investments made by particularly the FDA in the United States in upgrading all aspects of quality assurance programs.

A comprehensive quality control system for pharmaceuticals covers the following aspects:

- Procedures and standards for laboratory and clinical testing of the product prior to marketing.
- Procedures and standards for manufacturing the product once government approval for marketing has been granted.
- Procedures and standards for checks and controls in the distribution chain.

The foundations for the system are detailed records that can trace a given pharmaceutical product from the ultimate consumer/patient back to the earliest origins of its component parts through the various channels and intermediaries. A large amount of literature is available on aspects of these topics, including publications in WHO's Technical Report Series.

In this context, it is pertinent to quote the following item from SCRIP (1/14/78): "The World Health Organization's expert committee on specifications for pharmaceutical preparations deals with the problem of quality control testing of drugs that are imported by developing countries where there are inadequate technical resources. In its latest report (WHO technical report series 1977 No. 614), it proposes the development of simplified tests for widely-used drugs which require stable, easily obtainable reagents and unsophisticated laboratory equipment, which can be done by relatively untrained staff, and which provide a warning of unsuitability pending more thorough investigation."

The publication of this report should fill a particularly important gap in the quality control system of LDCs.

With few exceptions, notably antibiotics, biologicals, and insulin, most countries do not require a manufacturer to submit samples for analytical control by a government laboratory prior to releasing a particular lot for distribution. Reference samples, however, are normally required to be kept by the manufacturer for a certain amount of time after he releases a given batch of products for distribution.

Although governments in reality certify the quality of pharmaceutical products through premarket clearance, factory inspection, and distribution sampling schemes, manufacturers are still solely liable for the quality of their products. Thus, the extent of a manufacturer's quality guarantee is one measure of his integrity.

The growing quality demands on pharmaceutical products have tended to establish particular quality images for specific brands. In the process, the significance of officially recognized quality standards such as those contained in the various national compendia and pharmacopeias, including U.S.P. and B.P.--and also supranational ones such as the European and Nordic pharmacopeias--have lost stature and importance. This situation is a key reason why the banning, through government intervention, of brand names in favor of generic names is difficult to achieve without possible, and in the LDCs likely, repercussions on quality.

It seems clear that manufacturers of pharmaceuticals, including the large international companies, do not maintain the same comprehensive quality control systems for their products in the LDCs as in the developed countries. There are undoubtedly several reasons for this situation, but efforts by governments in the LDCs to rectify this situation, which has obvious implications for the overall quality of health care a country can offer, will probably only succeed to the extent of the strength of the government's intervention policy.

Another quality problem faces those LDCs that are pursuing a strategy of promoting indigenous remedies as part of its pharmaceutical armamentarium. Here the lack of compendial standards and the need to establish them provide barriers, especially in situations where the government is willing to pay for such products instead of spending its funds on "Western" pharmaceuticals.

One aspect of drug utilization, namely the purchase of pharmaceuticals by wholesalers, retailers, and institutions, and the prescribing patterns among physicians, have long been audited by private companies in a more or less comprehensive fashion in many (developed) countries. The largest firm in this auditing business, the London-based IMS International Ltd., has numerous branches and correspondents throughout the world, and provides its services on a private and confidential basis to chiefly pharmaceutical companies. This data provide key inputs to planning and decision-making in the pharmaceutical industry. A few governments purchase portions of this information, but with the exception of the United Kingdom and the Scandinavian countries, governments generally do not have a data base that compares with that available to the leading pharmaceutical multinational companies.

This deficiency is now being recognized, and government agencies have become increasingly concerned about the need for better documentation of drug utilization patterns and comprehensive information systems that can trace movements of pharmaceutical products through the distribution system, identify prescription and dispensing practices, and record abnormal events.

Thus, the utilization component in a comprehensive pharmaceutical supply system has emerged in recent years as a key problem area that takes into account all aspects of surveillance and monitoring of pharmaceuticals usage, not merely the consumption measured in monetary value or number of prescriptions.

Rational drug therapy may be defined as the mechanism by which the patient is given and treated with the appropriate drug entity in the appropriate dose form and strength, at the right time and for the necessary period of time, under proper medical-scientific supervision, and at a reasonable cost to the patient, his family, and society at large. The definition should also cover the concerns that an inappropriate drug be withheld from the patient, and that patients have

ready access to proper professional care where an inappropriate drug has been used and caused abnormal events.

By these yardsticks, empirical evidence suggests that rational drug therapy exists nowhere in the world, nor can it ever, and efforts to pursue rational drug therapy as a national goal would hardly be practical and certainly not cost effective. The variables involved are just too numerous and differentiated to be uniformly controllable.

Surveillance and monitoring systems in the LDCs are still in their infancy, and consequently it is not surprising that there are numerous accounts of "irrational" use of pharmaceuticals. Because of infrastructural weaknesses and other problems, LDCs will have to determine individually which policies and programs to institute in the field of drug utilization.

International conventions that aim at controlling the distribution of narcotics and psychotropics may provide precedents for similar agreements in other fields, for example, antibiotics where microbial resistance to older, well-known drugs now are common. However, the costs of ensuring compliance with such international conventions may be a deterrent.

Perhaps the most promising development in the effort to establish certain benchmarks for acceptable differences in drug utilization patterns is a policy statement on uniformly structured labeling by the International Federation of Pharmaceutical Manufacturers' Associations, which represents 40 National associations. The statement--reported in SCRIP (3/19/77)--urges manufacturers worldwide to issue full and informative labeling for products for all countries in which they are sold and includes the statement that "particular care should be taken that essential information as to medical products' safety, contraindications and side effects is appropriately communicated."

One should not expect uniform labeling by manufacturers to be a panacea, because physicians often use drugs for other than government-approved or manufacturer-suggested purposes.

The pharmaceutical component of any nation's total health care expenditures is large, but the costs of providing pharmaceutical products and services varies greatly among nations. Typically, nations in the developed world spend 6%-8% of their gross national product (GNP) on health care with 15%-20% of this sum being spent on pharmaceuticals. By contrast, LDCs usually only spend about 2% of GNP on health care, but 40%-60% of those expenditures are for pharmaceuticals. Thus, although pharmaceutical expenditures normally range between 1.0%-1.5% of GNP in both the developed world and the LDCs, in the latter the impacts on a national health care strategy from pharmaceutical policies are much more severe.

These ranges and benchmarks are only rough indices and should be used with caution. The reasons are that definitional uncertainties and discrepancies, lack of comparable statistics, likely double counting, differentials in inflation rates and currency fluctuations, and other factors undermine all efforts to perform truly comparative economic analyses across national borders in the pharmaceutical and health care fields.

One conclusion that may be drawn from results of various studies is that the price of pharmaceuticals is less important from a macro-economic perspective than the overall cost of drug therapy compared with alternative approaches. Another conclusion is that a high cost component for pharmaceuticals does not necessarily imply inefficient spending of overall national health care funds.

In his book, Planning the Health Sector--The Tanzanian Experience (1975), Oscar Gish writes that: "The question of controlling the cost of drugs to the health services in countries all over the world is one of the most perplexing of all those facing health service planners and administrators," and points to the interrelationships of pharmaceutical industry promotion and information,

physician education, lack of adequate financial controls, irregularities in the supply chain, etc. The following steps are then advocated as means by which the supply of pharmaceuticals can be controlled:

1. "A standard central medical stores drug list (a National Formulary) should be established with a view to reducing the number of different drugs circulating in the country at any one time; when additional drugs are added to the list it must clearly be shown that they are therapeutically necessary additions and well worth the additional cost.
2. The costs of the different drugs included on the standard list should be widely disseminated; and their generic names.
3. Attempts should be made to standardise drug prescribing for common ailments, especially at rural health centre and dispensary level.
4. A consultant's signature should be required for prescription of the most expensive antibiotics, as well as certain other expensive drugs. This would mean a restricted drugs list.
5. Prepackaging of standardised drug dosages should be established.
6. More rigid control should be practised over drug company representatives.
7. Various drug control proposals need to be implemented by special drug committees e.g., restrictions on the import of certain drugs, and use of local purchase orders for expensive drugs."

While these and many similar suggestions that have been made in recent years seem reasonable, there is little evidence that sufficient resources are available to carry out such policies as envisaged. The developed countries and also many LDCs have already tried that path and found that without viable measures to control the demand for pharmaceuticals, restrictions on the supply mechanism is largely ineffective from a cost containment standpoint.

The literature suggests that three methods of controlling the demand for pharmaceuticals must be an integral part of any cost containment scheme, namely patient copayment, increasing the physician's cost consciousness, and utilization review focused on doctors' prescription patterns. The latter method has perhaps most effectively been applied in the United Kingdom.

Integration with the health care system is the final component of the evaluative framework for a pharmaceutical supply system as developed in this manual. It alludes to the interaction of the system with other subsystems in the entire health care sector. Because of the differences among countries, it is not possible to measure the quality of this interaction according to simple objective yardsticks such as: pharmacist-physician-facilities-population ratios and numbers; consumption and utilization patterns; or price and cost parameters. One must therefore again rely on descriptive and judgmental methods.

The importance of the prescriber in the pharmaceutical supply system has been emphasized earlier in this manual, and one author, Paul V. Unschuld, points to the need for health care planners and decision makers to maintain a high level of professionalism for traditional health personnel: "Attempts to degrade formerly independent and respected practitioners to aids, auxiliaries, etc. of Western-trained personnel are doomed to failure. They are as offending to these people as are the terms "herbalists" or "quacks" that are applied to them by some proponents of Western medicine."

It is not clear whether this view is mirrored by or in conflict with the recommendations recently listed by a WHO Expert Committee on the Training and Utilization of Auxiliary Personnel for Rural Health Teams in Developing Countries. According to a WHO press release (12/22/77) the Expert Committee

feels that many functions normally carried out by Western-trained doctors, nurses or health technicians could be delegated to others, but under proper supervision; examples of such functions include the administration of injections, distribution of chloroquine against malaria, and administration of certain antiseptics.

The importance of the dispenser of drugs overshadows the importance of the prescriber in rural areas of LDCs, and judging from trends in community pharmacy practice in the developed countries, the role of the pharmacist as a member of the health care team is bound to grow both in the institutional environment and especially in primary care settings. This is the pattern in many LDCs already now and not a new thought. For example, in an AID-sponsored report on pharmaceutical services in Vietnam, Report of the Pharmacy Survey Team (1969), the authors state: "It is anticipated that a shift in emphasis from drugs as products to the dynamics of their use, the pharmacist can be a more useful member of the health team."

The same report provides good insights into the status of pharmaceutical services in a developing country and deals extensively with pharmacy manpower training and education aspects, and also comments briefly on the integration of traditional medicine with Western pharmacy practice. It concludes among others that: "Full realization of the benefits deriving from support of other health professions in Vietnam depends upon commensurate support of pharmacy."

The South Korean health care strategy offers an interesting example of a country that has invested the major portions of its health care resources in a pharmaceutical supply system. Today there are still 33% more pharmacists than physicians in South Korea, and while indigenous remedies continue to play a large role, acceptance of Western pharmaceutical specialties is growing rapidly. Virtually all pharmaceuticals are available over-the-counter, and there is no separation between dispensing and prescribing. However, in a leaflet describing three AID-sponsored pilot projects for new community health projects, the Korea Health Development Institute, Seoul, states (1977): "According to a study published in 1975, only 63% of the poeple in the rural areas who are ill have access to medical facilities, while the rest receive no treatment whatsoever. Among them, only 21% of the people obtain their primary curative services from modern hospitals or clinics and 8% from health centers; while 21% obtain their services from herb doctors or traditional resources, and about 50% are treated at pharmacies."

The Motivational Framework

The use of incentives for promoting the efficiency of health services was one topic explored at a seminar organized by WHO some years ago, and while the summary proceedings that were subsequently published in book form by WHO under the title Health Economics (Geneva, 1975) include some discussion that have general relevance to the pharmaceutical supply system the vast body of professional literature that deals with the behavioral sciences is equally pertinent.

Since attitudes, behavior, values, leadership styles, etc. vary widely among individuals and among societies, planners, and decision-makers who set the policies and parameters for a nation's pharmaceutical supply system may need inputs from the behavioral sciences before attempting to predict the outcome of specific measures. These and related topics are probably discussed in the socio-cultural manual published in this series of "Guidelines for Health Sector Analysis."

The research for this manual did not permit the development of a special framework for the motivational aspects of a comprehensive pharmaceutical supply

system. However, the manual would not be complete without at least pointing to these aspects as crucial elements in harnessing and nurturing the driving forces that shape the structure and quality of a national pharmaceutical supply system.

The more important forces have been mentioned, discussed, or alluded to throughout the manual. Motives such as profit, power, security, morals, humanitarianism, and man's thirst for new knowledge obviously operate in various forms within each component of the pharmaceutical supply system. Awareness and recognition of the motivational forces require communication as well as education.

In the private business sector, the profit motive encompasses concepts such as property rights and liability. The concept of private property rights appears to be subject to diverse pressures with the pharmaceutical patent system being strengthened throughout the developed world and weakened in the LDCs, while the trademark system is becoming subject to increasing erosion in both developed and developing countries.

Recent developments with regard to the simplification of the international patent application procedures are reported by IMS Pharmaceutical Marketletter (11/21/77) and SCRIP (12/24/77), and other information on the pharmaceutical patent system is easily available from the literature.

The pharmaceutical trademark literature is also very large and must be seen in context with nomenclature systems such as the WHO-sponsored INN (International Nonproprietary Names) and the American Medical Association-sponsored USAN (United States Adopted Names). Most recently, UNCTAD states in a report--cited in SCRIP (10/31/77)--that trademarks may be a more potent source of market power than patents.

Both the patent and trademark issue is discussed in a summary fashion in a booklet by Pharma Information, Basle, entitled, Legal Protection for Drugs (1975).

Industrial and government secrecy policies also affect private property rights. It is notable, therefore, that these policies are being relaxed in leading developed countries, a development that could have serious adverse impacts on numerous components of the pharmaceutical supply system.

Liability

With regard to liability, the other concept singled out for special mention here in connection with the profit motive in the pharmaceutical industry, the following paragraphs are quoted from the study Pharmaceutical Industry Dynamics and Outlook to 1985 (published by Stanford Research Institute in 1976):

"Product liability for iatrogenic damage is emerging as another intractable pharmaceutical problem which privately owned corporations will not be able to solve without public sector support. The issues are complex, and in recent years have received particularly careful attention in Sweden, Germany, France, Japan, and--now in connection with the swine flu programs--also in the United States.

One aspect of the problem is that legal systems and concepts vary throughout the world. Generally, two principles are recognized in damage suits: causality and culpability. Four parties can be at fault--patient, physician, manufacturer, government--but since the industry has been under public attack for so long, it is not suprising that the causality principle has emerged as the more important.

Another aspect of the problem is that government controls, however rigorous, do not entail any economic product warranty by the public sector, since this could lead to negligence among the three other parties that could be impossible

to place or obtain compensation for. In the past, the industry has accepted its full responsibility for product quality, but this risk is no longer commensurate with the profits obtainable, since liability is now being extended to include product use.

Three other factors further complicate the problem. First, government market preclearance procedures do not eliminate the possibility of such disasters as thalidomide--some say they increase it since the medical establishment may develop a false sense of security in the use of new pharmaceuticals following government clearance. Next, truly new products cleared for marketing in one of the major nations are now marketed more intensively throughout the world than ever before. Finally, serious side effects are more apt to appear only after extensive use of the new product, often over many years or even over generations. During recent years, many large-selling pharmaceutical specialties have been associated with new or more widespread side effects because of better or conflicting epidemiological data or new interpretations of scientific evidence, and since this trend will continue, there is a growing urgency for the industry to seek solutions to the liability problem internationally.

The models under development in Sweden and Germany provide clues to the type of solutions that can be installed on a national basis: forced liability insurance placed with designated carriers, industry insurance pools, and government limits on amounts of damage payments according to a variety of criteria."

No country has yet solved the problems surrounding pharmaceutical product liability through new legislative measures.

CHAPTER FOUR

PHARMACEUTICAL SECTOR PLANNING AND ASSESSMENT

Structured Approaches

Much information is available from the literature on the common approaches to planning and assessment projects in the health sector. While such projects basically comprise four major phases--the investigational/diagnostic/information gathering tasks; the analytical/evaluative tasks; the strategic and operational recommendations; and reiterative/monitoring/adjustment activities during project implementation--there is little agreement among authors on scope, sequence, or focus of these phases. The explanation for this lack of consistency appears to be that the particular characteristics of any given project are unique which when combined with personal biases on the part of analysts and planners provide insurmountable obstacles to uniformity of approach in the health sector.

This situation is particularly characteristic of the pharmaceutical subsector, where few, if any, systematic and comprehensive planning and assessment projects have been carried out on a national scale. This point is amply illustrated by studies that provide useful models for dealing with aspects and components of the pharmaceutical supply system.

While the manual lays out a logical and sequential approach to the pharmaceutical sector for comprehensive planning and assessment purposes, the author does not wish to imply that this approach is the only one worth following. This view is the more appropriate since the Agency for International Development (AID) has issued a circular, No. A-611, Procedures for Health Sector Assessments (11/20/76) which contains general guidelines for health sector assessments.

The "Quality Control" paper for this manual, prepared by Dr. Martin M. Rosner, outlines the following structure for an appropriate assessment process:

a. "Identify national health objectives and policies;
b. Identify health problems in the target population which can be remedied through rational drug therapy and rank them in order of prevalence, severity and economic impact;
c. Identify and analyze alternate pharmaceutical supply solutions appropriate to selected problems;
d. Identify and structure data requirements for decision making;
e. Identify and analyze administrative and infrastructure bottlenecks associated with particular strategies;
f. Analyze the social and cultural acceptabilities of various solutions;
g. Evaluate alternatives in terms of their probable consequences for attaining the characteristics required for an ideal pharmaceutical supply system;
h. Enumerate the probable consequences of implementing each strategy on the primary health problems identified in Step b, on interdependent parts of the PSS, and on interdependent parts of the general health sector;

i. Integrate all information on costs and benefits for the various alternatives including costs associated with making system changes and those associated with providing incentives for implementing the strategies; and

j. Synthesize the preceding steps to develop a comprehensive analysis of the various options. If appropriate, various strategies may be combined into integrated strategies."

Thus, as already stated earlier, it is clear that there is more than one "appropriate" structural approach to comprehensive assessment and planning projects in the pharmaceutical sector.

What may be feasible, however, is to develop guidelines for specific approaches to given "generic" types of projects dealing with similar aspects of the pharmaceutical supply system. Before such a "cookbook" outline can be drafted it would be necessary to at least review case histories showing what actually has been done in the past and whether successful projects show commonality of approach.

Methods

As there is no single best structural approach to the pharmaceutical sector, there is also no single best methodological approach to planning and assessment in this sector. Certain elements are, however, common to any good methodology.

First, the mission must be clearly defined. This is typically a much more complex undertaking than generally recognized and the project leader should be provided with sufficient time and opportunity to review the purposes, objectives, goals, and the scope and depth of the proposed assignment.

Second, when project parameters have been established as clearly as possible, a general report outline should be drafted and a supporting set of key matrices, tables, graphs, figures, etc. and questionnaires laid out in draft form. These aids should be looked upon as tools or as crystalized objectives, and they may contain qualitative or quantitative information, or a mixture of such "soft" and "hard" data.

In this connection, special reference should also be made to Volume III, Perspectives and Methodology (1972) in the series of studies and monographs published by the U.S. Department of Health, Education, and Welfare's Office of International Health under the common title, "Syncrisis: The Dynamics of Health." That volume will provide users of this Manual with valuable suggestions and examples of methods by which the population's health status can be ascertained, resource adequacy can be determined, cost/benefit equations can be approached, and much more.

Third, a focused literature search should be carried out in an attempt to gather as much secondary data as possible. The LDC client should assign appropriate staff to participate in this search since a majority of data will probably have to be retrieved in the LDC concerned.

Fourth, on-site field work is essential to verify, modify, and amplify secondary information, to design possible new data gathering efforts based on appropriate surveys, and to become generally familiar with the overall pharmaceutical dynamics in the country.

This phase of the study can normally not be accomplished with any success without the active participation and support of local professionals and/or research assistants and secretarial/clerical staff. Local assistance and participation is needed both to help solve practical problems for the foreign project staff (interview scheduling; interpretation and translation; accommodation and transportation; guidance in local customs, values, power structures,

conduct of field work, supervision of local consultants, etc.) and for the project leader to gain on-site perceptions as to what is realistically feasible and what can realistically be expected with regard to project completion and implementation.

Fifth, the report preparation phase should allow the project leader and the principal project participants sufficient time to prepare and discuss one or more drafts before a document is officially submitted to the LDC client and/or the Agency for International Development. The difficulties in preparing this report will naturally vary according to the scope and complexity of the project, but it may be generally assumed that the more effort invested in the first step mentioned above, the less effort needs to be invested in this fifth step.

Estimating the cost of carrying out a project focused on planning and assessment in the pharmaceutical sector is extremely difficult because each study is unique and so is each country. Thus, supposedly similar projects carried out in, for example, Ecuador, Gabon, and Indonesia will undoubtedly entail vastly different costs. As a general guide cost estimators should keep in mind that project work in LDCs tends to be more expensive than in the developed world, not only because of the scarcity of data and need to generate some "hard" information, but also because the productivity of professionals brought in from the developed countries tends to decrease after 2-3 weeks in an LDC; language and transportation problems often entail other unexpected costs.

In this connection, one cannot help but wonder whether a sufficiently adequate project is actually doable in many of the smaller and poorest LDCs within cost and time parameters that bear any reasonable relation to the amount of money the country spends on its pharmaceutical supplies.

Data Gathering and Analysis

The data gathering process is always fraught with pitfalls because sufficient detailed and reliable information is rarely available and can seldom be generated. Therefore, most projects must be completed and decisions ultimately made on less than perfect information. It is important, therefore, that the collection of data be organized in such a manner that the process becomes part of a comprehensive information system which can be maintained, upgraded, and expanded over time. This implies that forms should be developed to accommodate data bits at various levels of aggregation.

The need for data is never static; and since planning and monitoring pharmaceutical supply systems should be viewed as continuous activities, it is particularly important that raw data be preserved in such a manner that they can be retrieved and aggregated differently when the need arises.

In the LDCs it is particularly difficult to trace the evolution of pharmaceutical supply systems for lack of "hard" historic data. This deficiency in the data base also puts particular constraints on the planning mechanism since the absence of clearly visible past trends obscures the planner's vision of the future. Consequently, a data gathering effort focused only on the current situation is of limited utility.

All countries possess and regularly collect data pertinent to their pharmaceutical supply system, however, in many cases these data exist in isolated environments and are used only for the purposes of a few users. Therefore, the identification of these data banks becomes one of the primary tasks in planning and assessment projects.

Pharmaceutical data are found in all sectors and a checklist of possible sources should be developed, encompassing all the logical sources within the

government and within the private sector. The latter should include professional and trade associations of various kinds as well as major firms (suppliers and buyers) and major hospitals, and could also include service organizations such as banks (letters of credit often contain useful information), advertising agencies, insurance companies, freight carriers, and business publications servicing the pharmaceutical industry, trade, and profession.

Much of the data available in the public and especially in the private sector is, however, inaccessible partly because it is considered confidential and proprietary and partly because it is often not readily retrievable. Insofar as the private commercial sector is concerned, the reluctance to part with data is also related to concerns over possible repercussions (tax collection aspects; competitive advantages and strategies; securing of import licenses, etc.) that may flow from cooperation with government investigators.

Gaining some access to this data is less a matter of government pressure than of the investigator's interview skills and his abilities to share other data and insights that are valuable or pertinent to the interviewee.

Data sources outside the country should not be overlooked. Appendix D lists a selection of these in addition to those already mentioned in Chapters Three and Four. The Bibliography prepared as a part of this manual project provides further references.

One key aspect of a comprehensive pharmaceutical data gathering effort concerns the pharmaceutical marketplace as it is viewed by the pharmaceutical industry. The major elements in such studies evolve around the following points:

- Determination of demand. Here the analyst needs to be particularly careful that the product universe and the units of measure are well defined and consistent over time.
- Determination of major segments by therapeutic classification and product type, by geographical region, by customer category, by source of financing, by type of distribution channel.
- Determination of industry and distribution structures. This concerns clarification of the number of participants in the market, their shares of the total volume of business, and their strengths in the major market segments.
- Determination of pricing structures by cost component and mark-up from manufacturer's price to consumer price, and by customer category.

Appendix C includes several items that show how data of this nature can be presented in summary form.

Recommendations

While analysts need to have wide latitude in structuring their recommendations pertaining to the pharmaceutical supply system, it is desirable that those reports submitted to AID Headquarters in Washington, D.C. bear some structural resemblance; otherwise inter-country comparability becomes virtually impossible.

In this connection it is again necessary to recall that AID projects in the pharmaceutical sector may cover widely different topics, and that there are undoubtedly many items characteristic of specific types of projects that need to be emphasized. Additional work is required to group these typical AID-projects in "generic" classes and to single out the characteristics that lend themselves to international comparison.

Meanwhile, it is suggested that any project in the pharmaceutical sector provides certain basic information pertaining to an overall introduction to

and appraisal of the sector in a particular country. Matrix 1 shows one specific method by which this can be accomplished.

Further, it is suggested that analysts' recommendations should be structured in such a manner that the expected impact of any intervention on the pharmaceutical supply system can be quickly perceived by decision makers. One approach by which this may be achieved is shown in Matrix 2.

CHAPTER FIVE

DISTRIBUTION OF PHARMACEUTICALS TO RURAL POPULATIONS

The Pharmaceutical Supply Systems Manual has presented a comprehensive approach to developing a drug supply system in less developed countries (LDC's). In so doing, little detail has been provided to create a background against which problems and problem areas can be silhouetted and defined. This particular section will present in highly abridged and simplified form, information and detail concerning: LDC development, traditional vs western drugs and remedies, dispensers, logistics and distribution.

In the majority of LDC's the rural population accounts for from 75% to 90% of the national population. The rural population consists of strata of village communities containing from several thousand to perhaps only 100 people with many living in remote areas of the bush, jungle or mountains. Illiteracy abounds and the general lack of printed or written communications has resulted in dependency upon age-old conventions and traditional customs. Traditions govern all religious and social practices including birth, the upbringing of children, marriage, sickness and death. The farther away from larger centers of population where educational process have gradually become entrenched, the more reliance is placed on traditional methods of dealing with sickness and health.

Due the existence of age-old health practices supplied by traditional medicine men, herbalists, witch doctors and untrained mid-wives, it is apparent that village people and rural populations have not been deprived of some kind of health care. Whether effective or not, numerous remedies obtained by these practitioners from their rural environment have been in use for centuries. Many are useful and Western pharmacopeias and standard formularies list drugs obtained or distilled from those used by the untrained traditionalists.

Anthropologists and other sociologists reject the intrusion of western civilization into the cultures of remote rural village and mountain people. Nevertheless, and without aggressive practice on the part of practitioners and promoters of western ideas the rural people have come to realize that other ways of life and cultures exist beyond their accustomed environment. Is there any place on earth where a ground dweller has not seen or heard a plane flying overhead? Indeed smallpox has been eradicated throughout the world due to vaccinators penetrating practically all the remote areas and immunizing every inhabitant of the settlements found. In the interest of public health, literally armies have been recruited and trained in immunizing rural people against killer diseases in Africa, Asia, Latin America and other regions.

A beginning has therefore been made in introducing Western medicine to the rural people of the earth. This does not mean that Western or Allopathic medicine will immediately be fully embraced and traditional medicine will be

dismissed. But, with realization by the rural people, that some of the endemic diseases which they have endured have been suppressed or eliminated has come a beginning and sometime grudging acceptance of new and different medicaments.

Since mid-century and before, political upheavals have taken place throughout the undeveloped nations. Former national entities have been divided and subdivided. New regimes and heads of state have risen and beer overthrown. It is almost axiomatic that stability of new or old regimes can more readily be established and with it continuing support of a national constituency through the state providing better services. Among those services which can be most readily demonstrated and perceived is improvement of community health. Medical facilities, health practitioners, dispensers of remedies and the availability of those western drugs and remedies are important elements of national policies of all developing countries.

One fundamental that underlies the provision of drugs and medical care in a very poor undeveloped country is that all medical and health care of the rural population will be provided by the central government. There may possibly be some participation by regional or provincial government entities. There may be a vestige of public health activity and a few health centers may have been established. It will usually be found that voluntary agencies such as church groups and medical foundations have made a start in supplying drugs and a minimal degree of medical care to outlying villages. That experience should be utilized through establishing a co-ordinating and advisory council of these agencies that can assist in either developing an initial program or in advising on expansion of an existing operational activity.

At some point in planning it is necessary to make a number of assumptions. Assumptions will now be made in the case of a hypothetical impoverished country in Africa. "Country X" has limited funds as it has only few exportable commodities. Other natural resources are present but need capital investment for their exploitation.

Country X has one university in its capital city and must send graduates to foreign medical schools for training. It has a few urban centers with each having from one or two hospitals for the poor. Private nursing homes and clinics exist for the affluent merchants, politicians, land-owners and elitists. Doctors who have been trained abroad will usually not practice in rural areas and will only be found in urban centers. Supplies are meager and efforts to train nurses, nurses aides and other para-medical personnel have been desultory and not actively pursued. In addition, the percentage of the national budget allocated for health purposes is insufficient to improve health activities to the point where morbidity and mortality rates of the rural poor will noticeably decline.

We will now assume that a change has taken place in the attitude of Country X towards its national health program. It is ready, with the financial and technical assistance of UNICEF, WHO, WORLD BANK, AID and other donor agencies, to enter into a vigorous multi-year effort of improvement of health services supplied to its rural population.

It is likely that before venturing into a country-wide effort, a pilot program will be started to provide experience and to gather all-important statistical and other data. The reservoir of information obtained will be the source for fleshing out the skeleton organization to be briefly described.

We will assume that there exists a Ministry of Health or its equivalent, functioning as a section of another ministry. Also that through the efforts of an outside agency a census has been taken or estimated, delineating total population and the percentage in urban and rural areas. We will not here

consider the needs of the poor of the urban areas as local health centers are usually present for them to receive medical care. The municipalities in most cases shoulder this responsibility.

How then does this hypothetical government go about bringing care and drugs to the rural people?

Program Development

Establishment of an organizational infra-structure must be undertaken at an early stage. The operational director must have an efficient staff including a well-trained pharmacist. The size and characteristics of the staff will ultimately depend upon the extent of the distributional network to be eventually established. Sections of the staff will bear responsibility for:

I. Finance and budget
II. Procurement--inventory
III. Warehousing and shipping
IV. Evaluation--training

While each of the above (or others as the situation may dictate) has specific obligations, there must be strong bonds of interrelationship and communication between all sections. Most of the functions of the individual sections or departments will also be carried out in the field. The distributional network will contain regional warehouses and offices. Each regional warehouse will control a minor network of depots and sub-depots. The administration of any program calls for the availability of two basic resources. People and money. Assuming that the government has designated a person or persons to plan, develop and administer a program for distribution of drugs, the next step is the allocation of funds. To do this there must be a budget.

I. Finance and Budget

Budget development in highly developed and advanced countries is a complex process. However, even in Country X with modest goals for its initial efforts, the job will not be simple. At the beginning, in the absence of prior experience except for what has been reported by voluntary agencies, careful estimates of requirements must be made. These estimates must consider: the number of dispensers or outlets through which drugs will be distributed; the kinds and packaging of drugs to be regularly stocked; the annual use of each of the drugs: the original quantity of each drug to be supplied each dispenser; the original quantity of each drug required by each regional warehouse and its subsidiary supply depots that will re-supply village dispensers and other outlets; the original stock of each drug required by a central warehouse and the regional ones depending on geographical location and transportation.

It has been demonstrated in other rural situations that a modest selection of from 20 to 25 drugs and ointments are sufficient to provide palliative relief for most common ailments. WHO and AID can provide lists of drugs. In addition, the central government through its Ministry of Health should designate a committee of physicians, with equal representation from the private and public sectors, to make final drug selection. It should be emphasized that the basic drug list be as small as possible, in some rural situations the list should not exceed 25 items. More than that number will confuse village dispensers and complicate initial record keeping as well as re-supply. Cost is also an important factor.

Also to be considered is the filling of the entire distributional network at the outset and the anticipated annual requirements to keep this network continuously supplied but not excessively stocked.

An important consideration is that in Country X all drugs will come from abroad and must be shipped either by surface (sea), or air and in the case of a landlocked country, further by rail or truck. Transportation is a major problem subject to all kinds of delays including weather, strikes, availability of vessels, trucks etc. and with the ever-present risk of loss due to fire, flood, pilferage and force majeure.

Once the delivered costs of all drugs to be ordered are determined it is prudent to add an additional percentage (from 15% to 20%) to cover increases in price of the drugs as well as added transportation costs due inflation.

If shipments are to be covered by insurance such insurance should cover replacement costs. The insurance should be included in the budget.

Also to be included in the budget are costs of warehouse space at the central depot level, salaries of warehousemen, cost of utilities and internal shipping. The budget should also include at the central level the costs of an inventory control system. This will be more fully explained later.

The budgetary process in a developing country is difficult with numerous ministries competing for scarce funds. In Country X however with a commitment to health activities supported by outside sources of funds, negotiating the drug budget will not be overly difficult. It should be explained and thoroughly understood at top government levels of planning that once embarked on a health and drug distribution program, budgetary provision for this activity to be supported by the government, with or without outside funds must be continued for each succeeding year indefinitely and probably at an increasingly higher level of expenditure consistent with increasing needs and demands of the target population.

II. Procurement and Inventory

These selections have been linked. While separate accounting and procedural units may exist, there is unusual interdependence demanding collaboration of the closest kind. Development of a standard inventory calls for combined planning with procurement. The variety and quantity of each item to be stocked required (a) consultation with experts regarding selection of the assortment of drugs and (b) dosage of each to be dispensed and (c) size of package unit to be distributed.

The procurement process must consider whether government procedures already in effect in Country X are suitable for its purpose; if not, how to modify it for ordering drugs and whether there are provisions for emergency procurement. The procurement officer to whom authority has been delegated to commit Country X for expenditure of funds must be assured that the funds covering a specific procurement action are available and have been budgeted. Through the procurement action, those funds must be obligated or otherwise earmarked to pay for what is being ordered. Procurement through quotation or competitive bid will depend upon government policy. The latter method is preferred but is more time consuming. It is probably prudent to purchase drugs directly from well established manufacturers. In consultation with the chief pharmacists and whatever medical advisory committee may be available, decision should be made whether brand name or generically identifiable drugs should be specified.

Planning for procurement is a long range process. Estimates of required stock levels should be made for all stations in the distributional network; cost of procurement and delivery computed and budget approved; requests for bids sent out and bids examined, orders sent out and funds obligated. This

process including acknowledgement from suppliers will take the better part of one year. Delivery to Country X central warehouse will take from 9 to 12 months. Two years is a not unreasonable estimate of the elapsed time required for initial stock piling and for filling the distribution pipeline. It is also essential to prevent shortages occurring in the stocks of most used and essential drugs that sufficient back-up stocks be included in the original order; for delivery 3, 6 or 12 months following initial shipment. The procurement office must be constantly aware of fluctuating inventory levels in order to maintain a consistent stock of supplies.

Inventory control is a subject that is constantly being scrutinized and discussed by management experts: numerous systems have been developed. Most, however, agree that certain essentials be included in a basic record for each item to be stocked. This can be a simple index card, size 5 X 7", a loose-leaf page in a book, or in a more sophisticated system, in an appropriately coded segment of a computer.

The information to be included would be the name or names (brand or generic identification), the strength of the formulation, e.g. 5gm-10gm, 100-500mcg, 0.1%-0.2%, aqueous or other solution, etc., the number of dispensing units per package and similar information if in large quantity or case lots. Also to be included is the date a particular shipment was received with cost, source and identifying manufacturers lot number and/or date of expiration of potency. An end-balance system should be used for recording additions to stock or withdrawals--e.g. as below:

DATE	ON HAND	SENT TO	ORDER #	QUANTITY	BALANCE
April 10, 1979	152	Region Y	a-4211	25	127
April 15, 1979	129	Region Z	b-210	10	117
May 1, 1979	117	Received	PRD-632	150	267

It is advisable in the interest of control as well as security that in all warehouses, depots and sub-depots, where inventories are maintained, a duplicate inventory be kept in the control offices with additions or withdrawals simultaneously entered. Spot checks can then be made at varying intervals to be certain that supplies physically on hand compare with those on the record card and are not being issued without proper authorization. Any distributing warehouse, depot or sub-depot should have assigned its own separately identifiable set or order numbers for requesting resupply. Identification may be by a different letter prefix to a series of numbers of, for example from 001 to 1000--any request sent to a supplying warehouse or depot must have an order signed by a responsible officer together with an order number. All supplies sent from a supply source should be accompanied by a shipping voucher that specifies the quantity and description of the item or items with their cost. Placing a value on the supplies will impress warehousemen and other handlers that supplies entrusted to their care should not be handled irresponsibly. The shipping voucher will also serve as a check on the original request sent to the warehouse or supply depot, and if incomplete will indicate balance to be shipped.

Evaluation and Training

Evaluation of any national or local program requires first a declaration and objectives to be achieved in a specific time frame. In the case of Country X, such purpose might include the establishment of the distribution network with goals to be: numbers and effectiveness of dispensers in the field; utilization of drugs and remedies; and reduction in morbidity and mortality

Other goals could be development of a reporting system that would gradually become more comprehensive and useful. Evaluation will be an assessment of how well these goals have been realized in a given period of time.

Training

As stated earlier, efforts to introduce western medicine to village communities have already been made through mass preventive programs e.g. immunizations, B.C.G. testing, malaria control, etc. These were conducted by outsiders. However, for dispensing western remedies at the local level it is advisable that a person of each locality be used, either someone of their own village or at least from a neighboring community speaking the same dialect.

The central government, which in most LDC's must support health care to those in rural and primitive communities, must develop a decentralized training program. At first the program should be designed to instruct village dispensers in the diagnoses and care of a few illnesses common throughout the country and which comprise 54% or more of recognizable medical problems and for which initial supply of limited kinds of drugs will be furnished.

This paper will not go into the details of this training program nor what subsequent steps should be taken to continually elevate the quality fo care to be offered. Training becomes a matter of long range planning taking into consideration economic feasibility and availability of personnel equipped to train para-medical people in increasingly higher and more advanced levels of medical care.

As no program can function successfully for a long time without supervision, higher level supervisors going to the field will perform 3 functions. Supervision alone as an auditing or policing action is resented and can lead to unproductive negative reactions. However, when performed as part of a continuous in-service training program, very positive results can be obtained. While exercising this dual function, program operations can be observed at first hand and evaluation reports can be accurately reported.

Evaluation will then become a dynamic partner in the continuous cycle of evaluation--planning and implementation which must be at the administrative center of any flexible and effective program.

In the preceding pages, efforts have been made to provide insights into a few of the essential early steps to be taken in developing a national drug distribution network. The requirement of brevity as a part of a more voluminous presentation has not permitted elaboration of the important elements. It is hoped that some insights and direction will nevertheless have been provided to those who may pursue a venture of the kind so briefly described.

Appendix A

DEVELOPMENT PLANNING FOR A PHARMACY IN A SMALL HOSPITAL

The purpose of this section is to describe steps to be taken in planning and operating a pharmacy in a small hospital. Most of the material has been excerpted from DHEW Publication No. (ERA) 77-4403.

Architects and hospital administrators may find the suggestions and comments provided herein most useful when interpreted in consultation with a pharmacist. Because there is no typical hospital there cannot be a typical hospital pharmacy. Each hospital must solve its individual pharmacy planning and programming problems.

Location: Factors to be considered in determining the location of the pharmacy department are:

Flow of outpatients and traffic pattern through hospital.
Flow of raw materials and supplies into pharmacy.
Flow of dry products and services from pharmacy to patient areas and other departments, e.g., nurses stations, operating rooms and clinics.
Nature and frequency of demand for pharmacy staff services.
Area(s) required, including potential for expansion or inclusion of additional functions.

Space: Various recommendations regarding pharmacy floor space on a "square foot per patient bed" basis have been made over the years. Such recommendation will not be made here, because the functions of hospital pharmacies vary greatly and a standard system cannot be identified for hospital pharmacies in LDC's.

Pharmacy floor space needs are greatly influenced by factors other than bed capacity. Because of the generally heavy work load of outpatients in LDC hospitals the clinic capacity must receive equal consideration as bed capacity. Other factors to be considered will include: storage for drugs in bulk, and open stocks, storage of bottles, boxes and packaging materials, refrigerated storage, security storage for narcotic and exceptionally valuable drugs, compounding and packaging of special presecriptions: space must be provided for facilities for washing and rinsing of bottles and personal hygiene and in many localities water purification installations are necessary such as distillation equipment for supply of sterile water. Other space will be needed for record keeping and office.

Drug Distribution: The drug distribution function is that of carrying out the physicians medication orders. The hospital's medication system is organized to perform this function. The system involves ordering and stocking of drugs in the pharmacy in anticipation of needs; receiving and processing physician's orders; all physical handling of drugs including delivery and/or administering to patients. The pharmacist administers the pharmacy within the framework of hospital goals and policies and organizes his staff, financial and physical

resources in compliance with these policies and attainment of these goals. He must coordinate his activities closely with other members of the health team particularly nurses. In controlling this function the pharmacist develops standards of performance and should periodically evaluate performance against these standards taking corrective action as necessary.

A facility cannot be properly planned unless the work methods or drug distribution system is well understood. In the developed countries several systems are in use but for LDC's it was believed preferable to recommend one in general use described as a combination floor stock-patient prescription system.

In the combination system a relatively small number of drugs, about 20, are maintained in advance of need on the nursing unit. All other drugs are obtained for a specific patient after the physician has written and signed an order on the patient's chart. Drugs kept on the nursing unit, called floor stock drugs, are maintained and inspected regularly by the pharmacist.

This system is acceptable only if the pharmacist receives a direct copy, or sees and initials the original of the physicians order before the medication is administered to the patient. Emergencies are excepted.

Drugs to be dispensed on prescription orders are regularly maintained in the pharmacy, never on the nursing unit, and the nurse is required to requisition a supply for each patient. This permits the pharmacist to (1) limit exposure to theft and improper storage conditions, and (2) advise the nurse of any special instructions or precautions in preparing unit-doses for administration. It is useful to define the term unit-dose:

> A unit-dose is the ordered amount of drug in a dosage form ready-for-administration to a particular patient. The nurse is thus not required to do any measuring or mixing and concerns herself only with the physical administration of the drug to the patient at a specific time.

The drug distribution function is a broad general function which includes the following specific activities, by the pharmacist. Reviewing and editing drug orders; improves legibility; standardizes format, abreviations and terminology; ensures identical drug nomenclature for precise identification with that on label of drug products; converts and standardizes all measurements to metric system; identifies conflicting orders for resolution; monitors initiation and termination of orders to prevent overlapping orders and duplicate doses; reduces errors from verbal orders; detects potential drug interactions and prescribing errors; offers physicians recommendations regarding pharmaceuticals and cost of particular formulations; can quickly identify unfillable orders due unavilability of drug products; dispenses to inpatients and to outpatients; in the latter case, usually on a face to face basis permitting instructions regarding self administration of prescription drugs. The pharmacist also performs compounding to order, packaging and correctly labeling the product for immediate issuance or dispensing.

Other functions in the area of management and general administrations are performed either directly by or under the direct supervision of the pharmacist.

Purchasing

Operations commonly involved in purchasing include reviewing publications and catalogs which describe drug products commercially available; review of inventory stock levels; preparing the purchase orders; dispatching to vendor and completing purchasing records.

Receiving

Receiving assures that all drug products received from vendors or manufacturers are as ordered and properly entered in the inventory control system. Certifies approval for payment to supplier.

Inventory Control

Inventory control maintains standards for inventory quantity and quality, also detects and reports deviation from these standards. The standards must be defined or approved by the pharmacist. Inventory control must also include establishment of a reorder level for each item carried in stock. Periodic review of deviations from standards should be made and inspection instituted on a regular basis for signs of unsuitability for use. The pharmacist is also responsible for inspection of the environment, (cleanliness, humidity and temperature), maintenance of an inventory status file and attendant records.

Storage

Storage provides space and environmental conditions specified by inventory control standards for holding the optimum quantity of inventory units. The economically optimum number of inventory units to be kept in storage is theoretically calculable for each hospital, given such factors as the cost of placing an order, the cost of holding an item in inventory per unit of time (capital investment), quantity discounts from vendors, and willingness to risk outage. Unfortunately, too often the extreme shortage of budget, characteristic of government supported hospitals, dictates the level of inventory at certain times of the year. Proper planning can do much to circumvent such difficulties. Whenever the pharmacist cannot be assured that pharmacy stock stored outside his jurisdiction will be properly controlled for security and temperature, he must insist on control of the immediate areas in which his stock are stored or removal to a suitable environment. This may be the case where personnel from other departments have uncontrolled access to storage areas.

The foregoing has been presented to provide some perspective to those who contemplate including plans for a pharmacy in a small hospital in an LDC. With a brief description of the major functions of a pharmacy and its place within the overall operation of a hospital, it is anticipated that architects and planners will approach planning for such an activity with greater appreciation of its relative role in hospital operation and service.

For more detailed information we refer you to the publication from which much of the foregoing has been extracted. That is Planning for Hospital Pharmacies, U. S. Department of Health, Education & Welfare, Public Health Service. DHEW Publication No. (HRA) 77-4003.

Matrix 1

Country _____

SELECTED BASIC DATA ON THE PHARMACEUTICAL SECTOR

	1965	1975	1985	Real Growth in Percent 1965-1975	Real Growth in Percent 1975-1985	Inflation (%) (Where applicable) 1965-1975	Remarks
A. Demographic & Economic Parameters							
Population Size (millions)							
Total							
a. 0-18							
b. 18-44							
c. 45-59							
d. 60 & over							
Females (%)							
Urban Population (%)							
Number of cities							
Over 1,000,000							
Over 500,000							
Over 100,000							
Health Indicators							
Infant Mortality Rate							
Urban							
Rural							
Average Life Span							
Male							
Female							
Major Causes of Death							
Male							
Female							
GNP (Gross National Product)							
Total (millions U.S.$)							
Per Capita (U.S.$)							
a. Urban							
b. Rural							
CPI (Consumer Price Index)							
Gereral							
Food Component							
Drugs Component							

Matrix 1: (con't) Country _____

SELECTED BASIC DATA ON THE PHARMACEUTICAL SECTOR

	1965	1975	1985	Real Growth in Percent 1965-1975	Real Growth in Percent 1975-1985	Inflation (%) (Where applicable) 1965-1975	Remarks
A. Demographic and Economic Parameters (con't)							
HCE (Health Care Expenditures							
Total (millions U.S.$)							
Percent of GNP							
Government Share (%)							
Drug Expenditures							
Total (millions U.S.$)							
Percent of HCE							
Per Capita (U.S. $)							
3rd Party Financed (%)							
a. Government share (%)							
b. Private share (%)							
c. Donations (%)							
B. Health Systems Parameters							
Population having							
Access to care (%)							
Urban (%)							
Rural (%)							
3rd Party Coverage (%)							
Government Sources (%)							
Private Sources (%)							
Regular Health Checks (%)							
Health Manpower							
Physicians							
Practicing (%)							
Persons per MD							
Pharmacists							
Dispensing (%)							
Persons per Pharmacist							
Dentists							
Practicing (%)							

Matrix 1 Country_____

SELECTED BASIC DATA ON THE PHARMACEUTICAL SECTOR

	1965	1975	1985	Real Growth in Percent 1965-1975	Real Growth in Percent 1975-1985	(Inflation (%) (Where Applicable) 1965-1975	Remarks
B. Health Systems Parameters (con't)							
Health Manpower (con't)							
Nurses							
Registered, Active (%)							
Nurses per MD							
Other Paramedical (OPM)							
OPM per MD							
Midwives							
Lab Technicians							
Other							
Health Facilities							
Hospitals							
Acute Beds							
Oer 100,000 population							
MD Clinics							
Dental Clinics							
Pharmacies/Drug Stores							
Clinical Laboratories							
Systems Utilization							
Hospital Admissions							
Short Term Stay (%)							
Patient Visits							
MD offices (%)							
Pharmacists (%)							
Clinical Lab Tests							
Prescriptions Issued							

Matrix 1 (concluded) Country _____

SELECTED BASIC DATA ON THE PHARMACEUTICAL SECTOR

	1965	1975	1985	Real Growth in Percent 1965-1975	Real Growth in Percent 1975-1985	Inflation (%) (Where Applicable) 1965-1975	Remarks
C. Business Parameters							
Drug Demand*							
Ethical share (%)							
Property share (%)							
Number of Products							
Ethicals (%)							
Proprietaries (%)							
Number of Firms							
Manufacturers							
Domestic							
Foreign							
Wholesalers							
Retailers							
Pharmacies							
Drug Stores							
Hospitals							
Clinics							
Other							

*At manufacturer's price

Country_____

Matrix 2

IMPACTS ON THE PHARMACEUTICAL SUPPLY SYSTEM
FROM RECOMMENDED INTERVENTION

Intervention recommended:

Time and Cost Requirements:

The Functional Framework	(1975) Current Adequacy*	(1985) Future Adequacy*	Comments
1. Product Assortment			
2. Product Selection			
3. Procurement			
4. Domestic Production			
5. Distribution			
6. Inventory and Financial Control			
7. Pricing			
8. Product Information and Promotion			
9. Research & Development			
10. Financing			
The Evaluative Framework			
I Access and Demand			
II Quality Assurance			
III Utilization			
IV Cost Parameters			
V Integration with the Health Care System			
The Motivational Framework			
A. Driving Forces			
B. Private Property Rights			
C. Liability			

*Measured as high, medium, low or, if a more graduated assessment is feasible, on a scale of 1 to 10 with 1 being "bad" and 10 "excellent"

Appendix A

A Therapeutic Classification System

Reprinted by permission from the
Health Industries Handbook

(A continuing analysis and projection
service published by

SRI International, Menlo Park, CA)

Product Coverage--Pharmaceuticals

Central nervous system agents

- Analgesics
  - Narcotic
  - Nonnarcotic
- Antiarthritics (nonhormonal)
  - General, systemic
  - Gout products
- Anticonvulsants
- Antidepressants
- Antiobesity preparations
  - Amphetamines
  - Nonamphetamines
- Antiparkinsonism products
- Ataractics
  - Phenothiazines
  - Others
- Sedatives and hypnotics
  - Barbiturates and combinations
  - Nonbarbiturates
- Skeletal muscle relaxants
- All others

Gastrointestinal agents

- Antacids
- Antidiarrheals
- Antinauseants
- Antispasmodics/antisecretories
- Enzymes and digestants
- Laxatives
- All others

Neoplastic, endocrine, and metabolic agents

- Antidiabetics
  - Insulin
  - Oral agents
- Cancer chemotherapy
- Corticosteroids
  - Systemic
  - Local and topical
- Enzymes (excluding gastrointestinal)
- Oral contraceptives
- Sex hormones
  - Estrogens
  - Estrogen-androgen combinations
  - All others
- Thyroid therapy
- All others

Respiratory agents

- Antihistamines
- Bronchodilators
- Cough and cold preparations
- All others

Topical Agents

- Anesthetics
- Antipruritics
- Antiacnes, antiseborrheics, and related
- Antihemorrhoidals
- Ophthalmics and opticals
  - Opthalmics
    - Glaucoma therapy
    - Antiinflammatories
    - Antiinfectives
    - Miscellaneous
  - Opticals
    - Contact lens supplies
    - Decongestants
    - Artificial tears
- Vaginal spermicides
- All others

Antiinfective and antiparasitic agents

- Amoebicides and trichomonacides
- Urinary antibacterials
- Antibiotics
  - Cephalosporins
  - Semi-synthetic penicillins
  - Natural penicillins
  - Aminoglycosides
  - Tetracyclines
  - Macrolides
  - All others
- Sulfonamides
- Fungicides (including topicals)
- Antituberculars, specific
- Anthelmintics
- Vaccines and antigens
- All others

Heart and circulatory agents

- Antiarrhythmic agents
- Anticoagulants
- Beta-adrenergic blocking agents
- Digitalis and related cardiac glycosides
- Diuretics

Heart and circulatory agents (continued)

- Hypotensives
  - Rauwolfia/diuretic combinations
  - Rauwolfia
  - Other hypotensives
- Lipid-reducing agents
- Vasodilators
  - Coronary
  - Peripheral
- All others

Vitamins, nutrients, and hematinics

- Vitamins and minerals
  - Multivitamins
  - Pediatric
  - Prenatal
  - B-complex
  - All others
- Potassium and calcium supplements
- Hematinics

Proprietaries

- Analgesics
- Acne remedies
- Antacids
- Asthma preparations
- Cough and cold preparations
- Diuretics
- Hemorrhoidal preparations
- Laxatives
- Premenstrual tension preparations
- Sleep aids and calming agents
- Vitamins and tonics

Medical Supplies, Often Considered Pharmaceuticals

- Medical gases
- Intravenous therapy products
- Human blood plasma fractions
- Dressings
- Sutures
- Diagnostic products for *in vivo* and/or *in vitro* use
- X-ray supplies
- Dental supplies

Appendix B

Selected Issues and Approaches Relative to Local Production of Medicinal Chemicals

General Variables Among Medicinal Chemicals

- o Medicinal chemicals are used for human and animal therapy in prescription and non-prescription ethicals, and in OTCs; some are single-purpose, some are multipurpose entities.
- o Medicinal chemicals may also find use for non-therapeutic purposes as chemical process intermediates or solvents, in human food, in animal feed, and in cosmetics.
- o Old, modern, and very new medicinal chemicals; some are patented, most are not.
- o Medicinal chemicals have high, medium, or low process technology features.
- o Medicinal chemicals are produced by one of the four major processes: synthesis, fermentation, extraction, and purification/refinement.
- o Small volume but vitally needed medical chemicals versus large volume but therapeutically insignificant products.
- o Medicinal chemicals with complex molecular structures versus those with simple ones.
- o Families of medicinal chemicals with the same and with different production technologies.
- o Medicinal chemicals used in single and/or multiple ingredient preparations.
- o High cost and low cost medicinal chemicals.
- o Medicinal chemicals may be derived from simple and from complex starting materials; sourcing of these raw materials may be easy or difficult and their quality and price may vary considerably.
- o Products currently experiencing a low level of demand in a nation may be widely used in (for example) 1985, and vice versa.

Evaluation Methodology

Screening and preliminary selection of medicinal chemicals as candidates merely for local production feasibility studies require arduous work by experts with wide-ranging interdisciplinary competence. One method of approach to the initial tasks is outlined below. Ratings must emerge through a combination of quantitative and qualitative information, but judgment and personal biases will inevitably have a considerable influence on the outcome. Differentiation is feasible among the six criteria listed, provided the relevant priorities are clearly stated. All six criteria must be applied to each medicinal chemical included in the screen. Each criterion should be assessed on the same scale, for example, 1 to 9 with 5 being the average or--as below--1 to 3 with 2 being the average if the desire is to apply the "broad brush." The results of the evaluation should preferably include some indication of the confidence level the project team has in its assessments of the individual criteria so that planners and decision-makers may be able to judge the vulnerability of the preliminary findings.

A. This criterion considers the therapeutic importance of the product in medical care:
   1. Curative and/or life prolonging and/or considered indispensable for good treatment.
   2. Provides good symptomatic relief, perhaps with some prolongation of life.
   3. Not necessary for adequate treatment, although symptomatic relief might be provided.

Inevitably, these measures are often based on highly qualitative judgment.

B. This criterion estimates world dollar sales for a given year of all finished pharmaceutical preparations incorporating the medicinal chemical (price at specialty producer's level) and of all relevant "non-pharmaceutical" products:
   1. Over $150 million
   2. $75 million to $150 million
   3. Less than $75 million

C. This criterion attempts to estimate the world unit volume of demand--expressed in weight--of the substance. All applications should be considered. Estimates need to be made for the captive portion of the demand:

	Captive Share		
	Over 75%	25-75%	Less than 25%

1. Over 500 metric tons
2. 100-500 metric tons
3. Less than 100 metric tons

D. This criterion assesses the world demand outlook for the substance during a given future period; factors that affect the assessments include likely impacts from changes in technology (product and production), in health care systems and their coverage, in the regulatory and competitive environments, and a range of other factors that influence the demand and price for pharmaceuticals.
   1. Significant growth (about 5% per year)
   2. Stable growth (1%-5% growth)
   3. Declining demand (negative growth)

E. This criterion attempts to make preliminary judgments about the typical value added by manufacture (defined as the difference between total cost of materials and shipment value). The judgments should consider factors such as number of suppliers of starting materials and special processing chemicals, availability, quality, and price level of these raw materials, value of production know-how, quantities produced, patent status, and distribution system.
   1. High (more than 60%)
   2. Medium (about 40-60%)
   3. Low (less than 40%)

F. This last criterion is applied to the estimated number of world suppliers of products and technology in the given year.
   1. Few and/or only one producer of importance
   2. 3-4 important producers plus others
   3. Many producers--including a number of large companies

   Patented substances normally fall in the first group; large volume and/or "difficult to obtain raw materials for" substances usually fall in the second group and most others--the majority of which are medicinal chemicals used chiefly in the formulation of OTC preparations--fall in the third group. Depending on one's point of view, the scoring system might equally well be applied in the reverse order, i.e., "many producers" should rate a score of 1 and "few products" a 3.

Preliminary Feasibility Assessment

The following outline shows the basic information needed to form an initial opinion as to the feasibility of local production of a particular medicinal chemical, if produced in a single-purpose plant. Most of the data needs are the same for medicinal chemicals production in a multipurpose plant, but the overall economics change because overheads and capital investments can be distributed over more products--which again introduces greater pricing flexibility. The outline assumes that land for construction of the plant is available. Two estimates are suggested for each of the two examples of annual output (A and B):

the "low" estimate reflects the optimistic case, while the "high" estimate reflects the conservative case.

Product:

Assumptions: State basic assumptions relative to production processes and yields, forms and types of starting material, and other key factors affecting plant construction and operation in country "X" compared with the "international" situation.

A		B	
"Y" tons		"Z" tons	
Low*	High#	Low*	High#

Plant Cost (excluding land)

bricks and mortar
equipment
other
contingency (state %)
Total (state year)

Selected Questions

A. What are critical plant sizes and related output quantities (how is output related to total plant cost)?
B. What major types/size of equipment are needed for each production level?
C. Special requirements related to plant construction and/or location
   1. technical know-how--kind of rare skills needed?
   2. materials/equipment availability: any shortages or problems related to plant construction
   3. Availability of power and water
   4. Water treatment and other environmental considerations

Product Cost (preferably in U.S. cents per pound)

labor and maintenance
raw materials
utilities
other (specify)
Total (state year)

Selected Questions

A. Raw materials - (starting materials, solvents, intermediates, etc.) Are materials generally available (many sources with equal quality, price, and delivery considerations)?
B. Special know-how - Are special skills/knowledge needed to operate plant? Are there critical sub-processes requiring advanced techniques or knowledge?
C. Are there any saleable by-products that result from the production of this chemical?
D. For members of product families (such as sulfonamides) are there logical groupings--from a production point of view--which can be produced in one plant on essentially the same equipment?
E. For all products are there various production commonalities with other products or product groups which permit production of a range of products in one plant on essentially the same equipment?

Remarks and Conclusions: Discuss major "unknowns" and pitfalls in plant construction and operation. Can customers be found for the output? Assess merits of fullscale technoeconomic feasibility study. State the movements of "the international selling price" over the past five years, and discuss the future outlook for price changes. Who are the major competitors?

Appendix C

SELECTED AIDS IN PLANNING AND ASSESSMENT PROJECTS

I PHARMACEUTICAL DEMAND

Table I-A

PAST, CURRENT, AND FUTURE CONSUMPTION

Specialties	1965	1975	1985	Growth Trend*
Beginning Stock	$	$	$	
+Imports				
+Local Production				
(Sum)				
-Exports				
(Sum)				
-Adjustments**				
(Consumption)				
Raw Materials				
Beginning Stock				
+Imports				
+Local Production				
(Sum)				
-Exports				
(Sum)				
-Adjustments**				
(Consumption)				

*High - over 15%; medium - 10%; low - 5%. All annual averages.
**Deductions for ending stock, inconsistencies in basis of valuation (price levels, taxes and duties, discounts and samples, etc.) and improper product inclusions (medical devices, cosmetics, veterinary products, ordinary health care items, etc.)

Table I-B

ASSESSMENT OF PHARMACEUTICAL DEMAND OVER TIME
AND BY THERAPEUTIC STRUCTURE
(Manufacturer's Prices)

				Average Annual Growth*	
	1965	1975	1985	1965-1975	1975-1985
Therapeutic Category	$	$	$	%	%
Therapeutic Class					
Therapeutic Subclass					

*Growth rate measured in current values (i.e., inflation is included) but based on the same currency conversation rate (1$ = . . .)

Table I-C

LEADING THERAPEUTIC CLASSES WITH ABOVE-AVERAGE GROWTH PROSPECTS

	Growth %		Volume %	
10 High volume classes	Historic	Prospective	1975	1985
10 Low-volume classes				

(Similar table may be useful for below-average growth performers)

Table I-D

THERAPEUTIC PROFILE OF DEMAND

Therapeutic Categories	Percent of Total		
	1965	1975	1985
CNS	11%	13%	16%
GI	4	5	6
Etc.			

Table I-E

SELECTED BROAD FACTORS INFLUENCING
PHARMACEUTICAL DEMAND
1975 - 1985

Factors	Positive	Neutral	Negative
Regulatory			
Disease Patterns			
Demographic			
Medical			
Socio-Cultural			
Economic			
Informational			

Symbols: Positive + to + + +
Neutral 0
Negative - to - - -

II PHARMACEUTICAL USAGE PATTERNS

Table II-A

RELATIVE IMPORTANCE OF DRUG DECISION MAKERS, 1975

Prescribers	Ethicals	Proprietaries	Specially Restricted Drugs
Physicians			
Nurses			
Dentists			
Pharmacists			
Herbalists			
Midwives			
Paramedicals			
-			
-			
-			
Storekeepers			
Others			
	100%	100%	100%

Table II-B

PRESCRIBING PATTERNS IN SELECTED DRUG CLASSES
AND IN SELECTED SETTINGS, 1975

Gvt. Hospital/Clinic	Physician	Pharmacist	Other
Therapeutic Class			
-			
-			
-			
Private Hospital/Clinic			
Therapeutic Class			
-			
-			
-			
Retail Outlet			
Therapeutic Class			
-			
-			
-			

Table II-C

PROFILE OF DRUG THERAPY, 1975
(20 top-selling ethical drugs)

Diseases Treated with Top-Selling Drugs								

Table II-D

CURRENT TREATMENT OF MAJOR DISEASES IN AMBULATORY SETTINGS (1975)

Major Diseases	Diagnosis Made By*	Treatment Prescribed By*	Therapeutic Regimen+	Patient Profile**
-				
-				
-				

*
A: Physician
B: Pharmacist
C: Other Professional
D: Paraprofessional
E: Patient
F: Other

+Specify drug, daily dosage, length of treatment

**Infant, child, adolescent, adult, aged; male, female; first visit, repeat visit

III PHARMACEUTICAL INDUSTRY ORGANIZATION

Table III-A

BUSINESS ENTERPRISES BY TYPE, SIZE, AND NUMBER, 1975

Domestic Manufacturers	Large*	Medium*	Small*
Basic Production			
Domestic capital			
Foreign capital			
Joint ventures			
Formulation			
Domestic			
Foreign			
Joint ventures			
Importers/Distributors			
National Coverage			
Regional Coverage			
Retailers			
Pharmacies			
Drugstores			
Grocery stores			
MD clinics			
Hospitals			
Government			
Private			
Voluntary			
Other outlets			

*Each type needs definition, for example, in terms of turnover, staff, unit volume, etc

Table III-B

LEADING SUPPLIERS AND THEIR MAJOR PRODUCT STRENGTHS

Supplier's Identity	Total Drug Sales	(Selected major brands by therapeutic class with indication of the brand's market share)	
-			
-			
-			

(list the suppliers who between them hold a market share of 75%-85%)

Table III-C

PROFILE OF LEADING SUPPLIERS, 1975

Name	Corporate Sales: Non Drug	Corporate Sales: Drug	Years in Drug Business	Names of Major Drug Licensors	Perceived Strengths*: Government	Perceived Strengths*: Business	Perceived Strengths*: Professional
-							
-							

*"Significant," "moderate," and "little" may be used as descriptors

Table III-D

DISTRIBUTION SYSTEM FOR SELECTED THERAPEUTIC CLASSES, 1975

Therapeutic Classes	Indirect (through wholesaler) (all different types of outlets)					Direct (from manufacturer) (all different types of outlets)					Total Volume
	%	%	%	%	%	%	%	%	%	%	
–											
–											
–											

Appendix D

SELECTED INTERNATIONAL DATA SOURCES

SELECTED INTERNATIONAL DATA SOURCES
(not referenced specifically in the manual text)

Organization	Item
American Pharmaceutical Association 2215 Constitution Avenue, N.W. Washington, D.C.	1) Publications Guide 2) Listing of World Pharmaceutical Associations by Country 3) 1977 Pharmaceutical Directory
American Society of Hospital Pharmacists 4630 Montgomery Avenue Washington, D.C. 20014	World List of Pharmacy Periodicals--Revised and Enlarged Edition, 1975
Federation Internationale Pharmaceutique 11 Alexanderstraat The Hague, Netherlands	1) Survey of General Practice Pharmacy, 1974 (description of Pharmacy practice in about 140 countries in the world) 2) Drug Information Sources, A Bibliography by J.C. Bloomfield
Gothard House Publications, Ltd. Henley-on-Thames Oxon, RG9 1AJ, England	Drug Information Sources (1978) (A World-Wide Annotated Survey)
International Federation of Pharmaceutical Manufacturers Associations Nordstrasse 15 CH-8035 Zurich, Switzerland	1) IFPMA Membership Listing 2) Legal and Practical Requirements for the Registration of Drugs (Medicinal Products) for Human Use, 1976 (Handbook of drug regulatory systems in 45 countries)
International Pharmaceutical Students' Federation 248 Whitton Avenue East Greenford, Middlesex, England	Pharmacy Education and Apprenticeship in in 23 IPSF Member Countries and 1 Non-member Country (1975)
United Nations Publications United Nations Plaza, Room LX 2300 New York, NY 10017	1) United Nations Publications in Print, 1977--Check List 2) UNIDO Guides to Information Sources No. 20: Information Sources on the Pharmaceutical Industry.

*U.S. GOVERNMENT PRINTING OFFICE: 1979 O-300-481/6468

Volumes in International Health
Planning Methods - Guidelines for Analysis

1. Communicable Disease Control Planning
2. Environmental Health Planning
3. Health Manpower Planning
4. Socio-cultural Factors in Health Planning
5. Health Facilities Planning
6. Indigenous and Private Health Care Planning
7. Pharmaceutical Supply System Planning
8. Health Sector Financing in Developing Countries
9. Community Health Planning
10. Health or Wealth

Volumes in International Health
Planning Reference Series - Selected Bibliographies
and State-of-the-Art Reviews

1. Communicable Disease and Health Planning References
2. Environmental Health References
3. Health Manpower Planning References
4. Socio-cultural Facotrs in Health References
5. Pharmaceutical Supply System Bibliographies
6. Health Facilities Planning References